Dimensions of technology regulation

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Publication date:
2010

Document Version
Publisher's PDF, also known as Version of record

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Dimensions of Technology Regulation
Conference proceedings of *TILT*ing Perspectives on Regulating Technologies

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ISBN: 978-90-5850-511-8

Production:
Simone Fennell

Published by:

Wolf Legal Publishers (WLP)
P.O. Box 31051
6503 CB Nijmegen
The Netherlands
Tel: +31 24 355 19 04
Fax: + 31 24 355 48 27
E-Mail: info@wolfpublishers.nl
www.wolfpublishers.nl

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Abbreviations

ALARP	As Low As Reasonably Practicable
AmI	Ambient Intelligence
AmLaw	Ambient Law
ART	Assisted Reproductive Technologies
ASTM	American Society for Testing and Materials
ATMP	Advanced Therapy Medicinal Products
BMBF	Federal Ministry of Education and Research [Germany]
CNT	carbon nanotubes
EC	European Community / European Council
EFSA	European Food Safety Authority
EGE	European Group on Ethics in Science and New Technologies
ELSA	ethical, legal and social aspects
EP	European Parliament
EU	European Union
EMeA	European Medicines Agency
EPO	European Patent Office
ESN	external social networking
GM	genetically modified
GMO	genetically modified organism
HFEA	Human Fertilisation and Embryology Authority [UK]
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICT	information and communication technologies
ISO	International Organisation for Standardization
IVF	In-vitro fertilisation
MEP	Member of the European Parliament
NGO	Non-Governmental Organisation
N&N	nanoscience and nanotechnology
OECD	Organisation on Economic Co-operation and Development
OJ	Official Journal [EU]
OSN	online social networking
PGD	Preimplantation Genetic Diagnosis
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances
RFID	Radio Frequency IDentification
SCAN	Scientific Committee on Animal Nutrition
SI	Statutory Instrument [UK]
STS	Science and Technology Studies

SPA	Scanning Probe Agency
TR	Technology Regulation
TÜV	Technischer Überwachungs-Verein

Chapter 1. Introduction. A Dimensions Approach to Technology Regulation

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1.1. Introduction: a Multi-dimensional Analysis

From the first use of a stone as a hammer, the invention of the wheel or prehistoric man's ability to create fire, the extraordinary creative abilities of our species have needed controlling. The use of tools to adapt and control our environment, while the driving force of our species, has always presented human beings with the possibility of harming others, ourselves, or the broader environment within which we live. This endless creative and simultaneously destructive curiosity has always needed some form of regulatory control for the safety and benefit of both individuals and the community as a whole. These regulatory efforts seek a balance between encouraging and curbing innovation, requiring periodic adjustment where that balance tips too far in the permissive direction and we are reminded again of the destructive potential of our inquisitiveness; or it tips too far the other way and our playful inventiveness is stifled by unchecked fears. In recent years, the pace and range of technological change – a still accelerating phenomenon – has constituted a sort of 'permanent revolution', in which constant technological innovation and conversion across a wide spectrum of technologies has left our ability to adapt always one step behind. Regulatory efforts thus face an enormous challenge in keeping pace with technological developments and in finding an optimal balance between protection and creativity. While the complexities of technology regulation have long been noted, research into in this area as a comprehensive field of study worthy of its own disciplinary tent is a recent phenomenon; and one we are, un-surprisingly, still struggling to fully grasp.

The papers in this volume are an attempt to chart the nature of these complexities and to analyse regulatory responses to them. They are the result of an international conference organised by the Tilburg Institute for Law, Technology, and Society (TILT) in Tilburg, the Netherlands, on 10-11 December 2008. The conference title, '*TILT*ing Perspectives on regulating technologies', not only reflected TILT's ambition to bring together a wide range of international scholars that could shed light on the complexities and strategies of technology

regulation; it also conveyed the aim of the conference to address the challenges of technology regulation from alternative perspectives that have the potential to alter the angle from which we look at the field. These perspectives include those affected by disciplinary boundaries, by national background and by research interests.

The conference was organised as an open tent, in which speakers were invited from a range of different traditional disciplines – including law, ethics, politics, sociology, philosophy, management, policy and communication studies, science and technology studies, science proper and information security – from a range of national backgrounds, and without a preconceived overarching theme. What we most wanted to know from the conference participants was what their current preoccupations were; what aspect of the regulation of technology they found particularly challenging at present; and how they saw those challenges evolving as the technological revolution continues apace. The papers included here were selected to represent the range and depth of the themes that emerged from our discussions over those two days in Tilburg.

Through the open nature of the call for papers and the enthusiastic yet broad response, a number of themes emerged. These included a concern about the impact on individual fundamental values; a continuing preoccupation with risk and uncertainty, implicitly or explicitly paying heed to the well-known Collingridge dilemma (Collingridge, 1980);[1] a focus on the particular regulatory challenges in the area of nanotechnology and varying calls for sophisticated regulatory responses; reflection upon the broader societal implications of new technologies; as well as the way in which the technology-human dynamic may be changing human nature, making it necessary to re-consider what it is to be human.

The nature and form of this wide range of overlapping concerns, reflections and analyses have led us to visualise the contours of this emerging research discipline through the imagery of multi-dimensional space. In the final paper of this volume, Bert-Jaap Koops uses a metaphor borrowed from theoretical physics to present the discipline of technology regulation as a space that contains ten dimensions (Chapter 15, in this volume). In doing so, he attempts to provide a field manual to help us find our bearings in a multi-dimensional field and to guide us through it. Even where a ten-dimensional space is beyond

[1] This refers to the insight that the potential benefits of a new technology are widely accepted before enough is known about future consequences or potential risks to regulate the technology from the outset, while by the time enough is known about the consequences and possible harms to enable regulating it, vested interests in the success of the technology are so entrenched that any regulatory effort will be expensive, dramatic and resisted.

many of our imaginations, the analytical device of dimensions allows us, as Koops highlights, to gather our bearings and see more clearly where we are and what influences the determination of our positioning relative to others. Moreover, once we know better where we stand, we can move forward with more confidence into areas of the field that are yet to be explored, mapped and studied, and thus enhance our understanding of technology regulation *qua* discipline. As Brownsword and Somsen have recently noted, our regulatory intelligence remains primitive (Brownsword and Somsen, 2009:32); the final contribution of this conference, then, is to try and find new ways of understanding the emerging discipline of technology regulation as a way of beginning to think smart about regulatory possibilities.

Thus, in order to explore further this innovative approach to mapping the field of technology regulation research, we have decided to group the selected papers according to certain of the dimensions that Koops identifies. The aim is to better understand where we stand now, in order to be able to determine the research agendas of the future. For this purpose, we have been guided by the papers themselves and have identified the four dimensions of technology type, innovation, time and regulation type as best describing the authors' preoccupations and the way in which they approach what they identify as the most pressing challenges. Of course, each contribution is firmly grounded in the overall space and therefore touches upon many other dimensions, but the categorisation here serves well to draw out the scope of particular dimensions. While much remains to be worked out in arguing for a multi-dimensional approach, the organisation of this volume represents a first attempt to see how a dimensional tilt may contribute to our understanding of the emerging discipline of technology regulation.

This volume is grouped into four sections. The most obvious way to begin thinking about technology regulation is by reference to the technology type. Thus at the most fundamental level, we can divide technologies up according to the substance upon which they are based; for example, technologies of anorganic ('dead') matter (e.g., chemical substances), technologies of organic ('living') matter (e.g., biotechnologies), hybrids of these (e.g., nanomedicine), and technologies of information. The technology type will, to a certain extent, determine the type of regulatory challenges and where those challenges are located in other dimensions. For example, ICT is not only or even primarily located by reference to the hardware of the ICT machinery but by cyberspace, and thus by the dimension of place. Moreover, the regulatory response to a particular technology type may determine the response to a new technology based upon the similarity between types; for example, where the response to bio-medicine can

feed the approach to nano-based medical applications. The increasing tendency towards technological convergence, rather than rendering the dimension of technology type redundant, in fact invests it with a new importance: to understand the challenges posed by convergence, we need to grasp the relevance of technology type in all its dimensionality.

The second section is devoted to the dimension of innovation. Efforts to define the regulatory challenge posed by technology frequently refer to 'new technologies'. This is because new technology types, such as nanotechnologies or neuro-technologies, ask interesting new types of questions of regulators; however, 'old technologies' can also produce innovations that require regulatory intervention. Moreover, as suggested above, the regulator should not simply seek to respond to innovation but encourage it, or at the very least, seek not to stifle it. The challenge of creating a balance between stimulating creativity and controlling danger is located primarily within this dimension.

The third part of the book considers a perhaps underappreciated dimension of the regulatory landscape: time. Time, in relation to technology regulation, most obviously refers to the development cycle of technology: from fundamental science to applied science, and from product development to marketing and widespread usage. Different stages of the development cycle pose different regulatory challenges. Yet the time/knowledge disconnect coined by the Collingridge dilemma entails that technology and efforts to regulate it move at different speeds through time – a problem that is becoming more acute as innovation cycles get shorter. Technological innovation is thus accelerating away from the regulator. However, beyond consideration of the speed of innovation, focusing on the multiple elements of time can help us to grasp better the nub of a regulatory problem or see more clearly the ethical issues at stake, such as with the future non-existence – the missed life – of an embryo not selected for implantation.

The final section focuses on the dimension of the type of regulatory response. Moving beyond a narrow definition of regulation as law means that this dimension has multiple aspects. It contains not only different regulatory modes or tools but also the actors wielding them across the various levels and networks of governance (including the virtual), as well as those at whom the instruments are targeted. In particular, it also incorporates the differing ethical and cultural perspectives of various actors, both flexible and entrenched, and attempts to locate the interaction between the process and substance of a regulatory response. Moreover, this dimension also includes the use of technology as a tool of regulation itself (techno-regulation). Regulatory response is already relatively well plotted in comparison to other dimensions – for example, the explosion of interest in Lessig's

characterisation of techno-regulation as 'code as law' (e.g. Dommering and Asscher, 2006; Brownsword and Yeung, 2008; for the original, Lessig, 1999a: chapter 7; Lessig, 1999b) – however, the interaction between the multiple aspects of this dimension have not yet begun to be mapped adequately. Moreover, the further refinement of aspects of regulation type, as discussed by Koops, adds yet another layer to the complexity of our regulatory toolkit.

1.2. The Dimension of Technology Type

The three papers in the first section of this collection have been placed here in order to show different technology types and the way in which the properties of the technology itself determine the regulatory response. In the case of the first paper – a joint contribution by Esther Versluis, Tessa Fox, Anique Hommels and Marjolein van Asselt – the authors consider in detail the EU Seveso regime for the regulation of chemical hazard. The authors detail the particular hazards represented by industrial chemical production, both in terms of scale – the potential, when something goes wrong, for large-scale catastrophes such as Bhopal – and in relation to the nature of a chemical plant, in which the processing, storing and transport of dangerous substances works to inhibit risk, thus allowing risks to multiply. What these authors suggest is that the regulators in the form of the Seveso regime have misunderstood the nature of the risk at issue because they have misunderstood the nature of the technology. Whilst Seveso regulates on the basis of simple or singular risks ('the positivistic risk paradigm'), the chemical industry involves an interplay of multiple risk factors that are heterogeneous in relation to both place and time. This creates a complexity that the current regulatory response is not well equipped to deal with.

In reaching this conclusion, the authors provide a helpful overview of the development of the Seveso regime and the reasons for this regulation as well as a clear analysis of the content of the regulatory instruments that makes up the regime. To link this analysis to Dutch implementation of the Seveso regime, the authors conducted a series of in-depth interviews with actors on both sides of the chemical regulatory divide in the Netherlands. What these interviews strongly showed was that both sets of actors within the Seveso regime predominantly view risk from the classical positivistic model of risk as calculable and controllable, rather than as uncertain. This finding led the authors to conclude that the current Seveso regime has not learnt the right lessons from previous disasters and is not merely uncertainty-intolerant but 'uncertainty blind' – a potentially disastrous approach

given the nature of the technology and thus the potential for accidents to cause great harm in a single moment.

In the following paper, Jen Hendry and Kay Goodall consider the regulatory implications of a different technology, that of ICT. By focusing on the global phenomenon of Facebook, they consider the regulatory difficulties of privacy protection in an online world. The unique aspect of ICT – the fact that its most interesting properties reside not in the material aspect of the technology, as with chemicals, but in the virtual world they give rise to – has created unique regulatory problems. Regulators are struggling to adapt their tools to the altered reality of time, place and society that marks the virtual world. Hendry and Goodall approach this issue from the relationship perspective not of peer-to-peer interaction but that of provider-to-user. They take as a case study the Terms of Use that every user must sign up to in order to create a profile on Facebook and, in doing so, bring to light the staggering license that this grants to the provider. While content ownership remains with the user, the sweeping scope of the license grants Facebook the right to do whatever they like with the content for any reason they chose, even where it belongs to a former user, i.e. someone that has since closed their profile.

In taking this focus, they draw out the acute problems of regulating for privacy by comparing the attempt by some users to achieve privacy-related goals under different legal systems. In particular, the Terms of Use raise interesting questions of jurisdiction, asserting as they do that, without regard to existing principles on the conflict of laws, the law of the State of California applies to any and all disputes arising from using the Facebook site. Hendry and Goodall examine whether such a clause and that granting the provider the licence to use all user content would stand up in court on either side of the Atlantic, particularly given such questions as the age at which one can consent to a binding agreement. What their analysis reveals is the difficulty of seeking to protect privacy with the traditional tools of intellectual property and contract. The particular problems that arise relate to the discrepancy between concepts such as 'author' or 'owner' within different jurisdictions; and the difficulty in selecting a legal location in which disgruntled cyberspace users can challenge the overreaching licence conditions of the networking site or appeal to privacy protection rights. As with the previous paper, Hendry and Goodall suggest that the regulatory response has not yet grasped the challenges the particular technology poses, in this case, to fundamental rights.

An entirely different set of regulatory issues is raised by Bärbel Dorbeck-Jung in her contribution. Dorbeck-Jung's paper examines the particular regulatory challenges posed by nano-technologies, what she wittily terms its 'wicked governability problems'. Focusing on the

uncertainty of the risks posed by nano-medical products, she reasons her way to regulatory suggestions by means of comparing technologies and their regulatory frameworks. Her starting point is the EU's medical product regulatory regime and in particular the Advanced Therapy Medicinal Products Regulation. By comparing the governability problems of nano-medical products with the regime already in place, Dorbeck-Jung is able to highlight the regulatory gaps in relation to the particular problems of nano-based medicine; and, moreover, to suggest, where sufficient comparability exists, how the successes of regulation in relation to one technology can be applied to another. Moreover, the results of her analysis clearly influence her approach to bridging the uncertainty gap. Dorbeck-Jung argues that balancing the level of uncertainty inherent to nanotechnology with the extraordinarily high anticipation of the gains from nanotech in the medical field is only achievable by a form of hybrid regulation.

At the European level, hybrid regulation of nanotechnology takes the form of co-regulation and soft-law methods. These formats are understood as allowing for greater reflexivity and experimentation and thus as being better able to cope with uncertainty. Dorbeck-Jung goes on to lay out a number of questions that hybrid regulation must answer in order to be effective and legitimate, rotating around a number of core principles that she identifies as central to European regulatory ambitions, namely openness, accountability, proportionality, subsidiarity, coherence and vigilance (which could perhaps otherwise be expressed as precaution). The paper concludes, however, on an important cautionary note amongst the various calls for softer, *de facto* or hybrid forms of regulation; her case study of EU regulation of nano-medical products strongly suggests the need for centralising product knowledge, particularly in situations of de-centralised or hybrid regulation. This warning about the weaknesses of regulatory de-centralisation is picked up by subsequent papers, notably that by Gammel, Lösch and Nordmann in the following section.

It is worth noting, although it is perhaps apparent, that Dorbeck-Jung's contribution could be approached in this volume equally from the position of regulatory type; her notion of hybridity sees her tapping into a broader and more-established stream of work on hybrid or network governance methods at the global level. However what this paper nicely shows for our organisational purpose is that examining the interaction of technology and regulation from the dimension of technology type can also allow for comparison between the successes and failures of 'old' technologies or at least those technologies that are further along in the product cycle and where the risks are better understood. What her paper, further, suggests is that a focus on

technology type need not automatically lead to the uniqueness of different types of technology as the starting point of analysis.

1.3. The Dimension of Innovation

The second section of the proceedings opens with an impassioned plea from Wolfgang van den Daele to defend the liberal regime of innovation from populist fears of technological development. In the paper, Van den Daele charts the history of resistance to technological developments whilst making a strong case that it is a central tenet of liberalism that the benefits of technological progress outweigh the creative destruction that is inevitably part of conceptions of progress. In supporting liberalism's belief in the benefits of science, Van den Daele takes on the challenge that the precautionary principle poses to this regime. The precautionary principle, he argues, is too often used to plug the regulatory gap created by a lack of full scientific certainty. For Van den Daele, such a radical interpretation of the precautionary principle shifts risk assessment away from experts and bases itself instead upon popular perceptions of risk, leaving little room, he argues, for the right to innovate or for the freedom to act as long as it does not harm others.

Van den Daele's response to those who would wield human dignity as a trump card to prevent developments offending their moral sentiments, and to those who wish to see innovation made subject to public planning rather than left to market forces, is a plea for precaution with principle and for the recognition of the right of private innovation within a reflexive society. This proposal links back into an issue that was raised in the context of the conference, but that for reasons of space could not be developed in the present volume, concerning the responsibility of innovators and scientists for their own innovations.[2] While Van den Daele notes that the quest for responsible innovation should not leave the task of regulation entirely to innovators, he advocates an approach that has much in common with the *de facto* hybrid regulatory regimes that have sprung up in relation to nanotechnology, in which public and private actors co-operate to avoid the worst of the destructive forces of technological creativity. He ends, however, with a useful corrective to the fears and the related

[2] On the first day, David Richard Koepsell addressed this point explicitly in a paper entitled, 'On genies and bottles: scientists' moral responsibility and dangerous technology', in which he argued strongly that scientists themselves must take moral responsibility for the work they do, using examples such as the decision to continuing work to develop more lethal versions of the smallpox virus rather than destroy it once and for all. Arie Rip's paper, included in this volume, also reflects upon the individual responsibility of scientists and innovators to avoid harm.

demands for further regulation that dominates our present relationship with technology: whether a new technology is worthwhile pursuing is ultimately a question of private freedom.

The second paper in this section approaches the dimension of innovation from a very practical perspective. The contribution by Maurice Schellekens focuses on issues relating to the patenting of nanotechnology and in particular the need to find an intellectual property regime capable of balancing the uncertainty of risk with innovation in this field. In place of Van den Daele's defence of a right to private innovation, Schellekens warns of the danger of over-patenting in the area of nano developments, reflecting upon the harms that would result and suggesting moderate reforms to the patent system in order to prevent this from occurring. Similar to Dorbeck-Jung's reasoning, Schellekens bases his expectation that nanotechnology is likely to suffer from over-patenting on the parallels between this new technology and the somewhat older field of bio-technology. The evidence that patents are being granted on simple nano-particles, the building blocks of the technology, is similar to the conferring of patents upon individual genetic markers, according to Schellekens. Also similar is the way in which nanotechnology cuts across industries, with applications in a wide range of applied fields. As Schellekens nicely highlights, the cross-cutting nature of the technology is likely to entail not only that patent applicants are unaware of related developments in different fields, but also that patent assessors may be equally ignorant when deciding whether to grant or deny a patent, the likely result being patents that significantly overlap. Over-patenting in such a new and uncertain technology will stifle innovation as innovators struggle to pay the many multiple licenses that will be necessary to conduct basic research in the field. Given the anticipated benefits of nano-applications, avoiding such a scenario should be a top priority for regulators at every level. The call here, then, is for a balance between patents as a spur for innovation and the stifling of basic innovation from which we all stand to benefit, between private gains and broader public interest.

The third and final paper placed within the dimension of innovation also focuses on nanotechnology. Stefan Gammel, Andreas Lösch and Alfred Nordmann, a team of researchers working at Darmstadt University, continue upon the theme of innovation and nano-technology, picking up on Schellekens' concerns in an attempt to design a model of regulation that allows for continuing innovation in the field with a commitment to social well-being. The authors start from the premise that huge uncertainties about the risks of nano-technologies as a consequence of a lack of knowledge surrounding the potential toxicity of the technology and any subsequent products entails that formal means of regulation – i.e. legally set thresholds – are not a

regulatory possibility at present. As subsequent contributions detail (notably that by Van Calster, Bowman and D'Silva, and by Rip), the authors note that the classical regulatory model has been replaced by soft regulatory tools, such as observation, voluntary codes of conduct and stakeholder discussions. However, in contrast to the optimism of later contributions and of Dorbeck-Jung, the authors of this German-based study found that these softer forms of regulation not only could not meet the challenges of regulation alone – a point unlikely to be disputed by Van Calster, Bowman and D'Silva or Rip and one also highlighted by Dorbeck-Jung – but that, further, they do not satisfy the basic needs of regulation, which they understand to be public oversight, transparency and legal certainty.

In place of a drift towards softer regulatory forms in the absence of being able to opt for a more classical state-based model, Gammel, Lösch and Nordmann call for a reflexive adjudication procedure. This procedure is to take the form of a collective learning process, whereby existing regulation is subject to open and public critical scrutiny overseen by a special institution, which they provisionally term the 'scanning probe agency'. This agency is conceived as a 'learning community', under the auspices of which experts from all relevant sections of society would be drawn and brought together. Their role would be to investigate and judge nanotech products and processes of development and to present those findings to the public. The remainder of the paper is dedicated to outlining the tasks and working methods of such an agency.

Firstly, the authors highlight the large number and wide variety of products that are placed under the heading of nano-products; the uncertain and necessarily discursive nature of the heading 'nano-technology' itself demands a reflexive investigatory process. Secondly, the nature of nano-particles means that the traditional method of regulation – that of standardised testing of components – will not be successful in this context. Rather, the potential risks of a product will need to be monitored throughout the product's life cycle, and the public need to be made aware of the considerable uncertainty that is thus inherent to any licensing procedure as innovation continues to outrun our ability to comprehend the risks entailed. Further, the integration of nanotechnology in a wide variety of products means that calculations of risk will need to take into account the possible inter-action between products, variations in individual usage, etc., i.e. the multi-faceted nature of innovation procedures. Finally, given the wide range of possible applications for nanotechnology across the scientific spectrum, regulators need to avoid the danger of a fragmentation in perspective, so that in one context, a nanotech product is viewed from a chemical-toxicological perspective, and in another from an occupa-

tional health standpoint. A dedicated agency, so the authors argue, would be able to develop the necessary integrated and multi-dimensional approach to understanding the risks of innovation in this field.

1.4. The Dimension of Time

The third section focusing on the relevance of the time dimension to the relationship between technology and regulation opens with a contribution by Colin Gavaghan. In his paper, Gavaghan examines the 2008 UK Human Fertilisation and Embryology Act updating existing embryo regulation against a concern for the obligations we owe to future individuals and the issue of identity that such questions raise. While the legislation has produced a predictably polarised response thus far, Gavaghan ignores this debate to focus on the ethical concerns surrounding Section 14(4)(9) of the 2008 Act that requires that embryos known to have a significant risk of 'serious physical or mental disability' must not be selected over those that do not. While ostensibly straightforward – what kind of parent would opt for a child with serious disabilities over one without when faced with the choice? – Gavaghan shows that the intuitive response misses the ethical question that lies at the heart of this clause, that of the best interests of the not-selected embryo, the child not created. As he succinctly highlights, the issue is not one of improving the life of a child by opting not to allow it to be born with serious physical or mental disabilities but of replacing one potential child – a disabled child – with another potential, healthier child. Gavaghan's paper examines philosophical efforts to justify this choice and shows up the ethical inconsistencies attached to the common focus on the obligations of parents towards a 'generic child'. Instead, as Gavaghan notes, each embryo is a potenital individual and the parents' decision of non-selection does not offer it a better, healthier future but destruction. In this way, by focusing on the issue of time and our (mis)understanding of future (non-)existence, Gavaghan brings the ethical dilemma of the Act's disability clause sharply into focus and ultimately calls its legitimacy into question.

The second paper in this section focuses not on how we misunderstand future possibilities by focusing on immediate concerns but highlights the way in which we take time, and in particular the time for comprehension and reflection, for granted. In an intriguing contribution, Mireille Hildebrandt reflects upon the tandem development of the legal system in the Western world with the advent of the printing press. She argues that the dissemination of law as written word has allowed not only for the foundation of the modern state, in enabling a ruler to extend her, most frequently his, jurisdiction over a large territory (Berman, 1983), but that it has also been

instrumental to the development of rule by law and the rule of law. Central to Hildebrandt's thesis is the work of Paul Ricoeur and his claim that distantiation is inherent to script, that is that the written word allows for distance in both time and space due to the need for interpretation. As the law is written down and disseminated, the author loses control over its meaning, opening up that meaning for discussion and alternative interpretations. The possibility of multiple interpretations builds hesitation and space for reflection into our appreciation and application of the law.

Hildebrandt's view of law as being at a crossroads – her concerns for the future – relate to the increasing use of Web 2.0 technologies by 'digital natives', i.e. those who were born into a world of parallel processing that characterises the era of real-time computing. She fears that the speed and instant nature of communication are replacing delay, which, while positive in a number of aspects, simultaneously removes the opportunity for the critical assessment of information. As such, the younger generation are not developing the skills associated with linear sequencing and Hildebrandt sees in this development a dramatic challenge to law as we know it. In particular, the removal of distance and the necessary interpretation that accompanies it poses a very real threat to values fundamental to the 'old' or 'current' legal order, such as the protection of privacy, the principle of non-discrimination and the architecture of due process.

Further illuminating the relevance of time in the regulation of technology, the final paper in this section, although sub-titled 'the challenges of contemporary technosciences', speaks to a future-immediate world in which science will be all-pervasive. This paper by Hub Zwart explores the concept of pervasive science and the challenge that this represents not only for governance efforts but also for the possibility of individual self-management and our understandings of what it means to be human. As such, the concept of pervasive science poses a huge challenge to common understandings of humanity, nature and the purpose of society. Zwart develops the notion of pervasive science from Goethe's famous statement about nature; for Zwart, similar to Goethe's conception of the force of nature, contemporary techno-sciences surround us, interact with us, with each other, cannot be separated from us, and yet we have no power over them. This apparently terrifying view of the future thus characterises techno-science as pervasive, not only in their interaction with humans but also in their interaction with each other. Zwart notes that it is no longer possible to maintain the old compartmentalisations – such as between pure and applied science, between different branches of science, between nature and technology, etc. – in the face of the unstoppable blurring of these boundaries. This blurring is partly a

consequence, Zwart suggests, of biomesis, in which man-made systems are inserted into 'natural' systems in such a way that the artificial elements become embedded, challenging our conceptions of artificial and natural. This Faustus-like ambition to transcend nature, to improve upon it, will take us down a path in which we begin to blur the divide between nature and man-made and in which the distinction between Self and technology itself becomes more than a little hazy. In this paper, Zwart presents concrete examples of fields and applications where this is likely to occur in the future and notes both the opportunities and dangers that these avenues present society and our attempt to make sense of the technological revolution. The tone of this paper suggests that there is no going backwards, no stopping the role of science in our lives and its potential to alter human nature itself.

1.5. The Dimension of Regulation Type

The four papers in the final section of the volume have been placed together to be viewed through the prism of regulation type because they represent different regulatory perspectives, providing alternate insights into the regulatory tools available, as well as the pros and cons of different approaches to technology problems.

The first paper is a joint effort by Maastricht-based colleagues, Marjolein van Asselt, Ellen Vos and Tessa Fox. It focuses on the process of regulation and the crucial importance of the influence and attitude of individual actors in determining a regulatory outcome, in particular the role of the European Court of Justice in interpreting and applying policy-type recommendations. This paper builds upon the earlier work of Van Asselt and Vos on what they have termed the 'uncertainty paradox' in the field of risk. They see this paradox of uncertainty – a term for situations in which uncertainty is acknowledged but where science is presented, by policy-makers and judicial actors, as capable of providing certainty – as particularly pertinent to new technologies.

In responding to the challenge posed by the Collingridge dilemma, the authors identify a need to focus more closely on the attitudes of actors involved in the processes of risk assessment and risk management. By examining four cases of technological regulation at the European level – namely the Pfizer case and three cases from the saga of EU GMO regulation – they detect a distinction between attitudes that are normally labelled simply as either risk adverse or non-risk adverse. Instead, Van Asselt, Vos and Fox develop the notion of uncertainty intolerance and show that where, in the Pfizer case, crucial actors are both risk adverse *and* uncertainty intolerant, in the GMO cases, the critical actor is uncertainty intolerant but non-risk adverse.

What the authors discover by contrasting these cases is that what is often considered to be risk aversion is, as in the case of GMOs, risk intolerance, i.e. an unwillingness to consider the possibility of uncertainty. Moreover, what their analysis shows is that an attitude of uncertainty intolerance held by a critical actor in the process of either risk assessment or risk management is what made uncertainty intolerance the dominant feature of regulatory efforts in all four cases. This study suggests that the psychological attitudes of the main actors towards uncertainty play a critical role in the design and implementation of technological regulation, and, as such, is an area in which much more research is needed.

The second paper reviews the suitability of EU legislative instruments in the area of nanotechnologies. The collaborative paper, based upon the first year of a four-year research project at the Catholic University of Leuven, examines the regulatory framework at the European level across three separate industries – cosmetics, medical applications and food contact materials – to determine the extent to which regulation is problematic and the ways in which the regulatory regimes in each case determine, assess and manage risk. In doing so, Geert van Calster, Diana Bowman and Joel D'Silva pick up on some of the concerns raised by Van Asselt, Vos and Fox, namely that the very novelty of this new technology and the considerable array of potential benefits it offers has persuaded governments and industry to allow experimentation across the manufacturing chain despite the new and unpredictable risks attached to such a new and untested technology.

By means of case-studies, the authors identify a regulatory gap caused by a lack of scientific data on the mid- to long-term effects of products containing nano-particles. Further, this lack of scientific information has, according to the authors, been used to avoid taking any clear regulatory steps, with the European Commission opting instead for an incremental approach of amending existing instruments. The result, according to Van Calster, Bowman and D'Silva, is that regulatory authorities at both the national and the EU level have turned to softer instruments to respond to the particular challenges of regulating nanotechnology. Where national authorities have generally focused on the possibilities of voluntary reporting schemes and similar programmes, the European Commission has been slightly more innovative. In place of voluntary reporting, the Commission has, in consultation with a variety of partners selected from across industry, academia and civil society, developed voluntary Codes of Conduct, i.e. not simply self-monitoring but self-regulation. While, as the authors are quick to highlight, the effectiveness of such systems of self-regulation are yet to be determined, self-regulation as a supplementary framework to that of traditional 'command and control' regulation looks

promising. The next phase of the Leuven project is to move beyond an academic consideration of the regulatory frameworks in the three areas of cosmetics, medical products and food contact materials and to identify benchmark criteria for regulatory nanotechnology – a step further towards reducing our uncertainty about nanotechnology regulation and one that is therefore eagerly awaited.

A focus on the utility of self-regulation in areas of high uncertainty is picked up by the following paper in this section. The contribution by Arie Rip, a veteran of the field of Science and Technology Studies, highlights the extent to which, in the absence of legislators taking the lead, *de facto* governance mechanisms are in fact springing up in the area of nanotechnology at all levels of governance. Given the structural uncertainties highlighted by others, what surprises Rip is the extent to which nanotechnology is already being governed, albeit without any particular actor with a clear agenda being responsible for such activities. Rip's contribution is thus concerned with charting the extent and nature of, and the interactions between, the various actions that are currently functioning as *de facto* governance arrangements in the field of nanotechnology. Here he provides necessary clarity to the emerging pathways of interactions of and between soft regulatory forms, and charts, by means of a helpful diagram, the development of these forms over time.

The second and broader part of Rip's paper takes elements raised in the preceding paper further and is concerned with considering how and when *de facto* governance arrangements are successful in achieving regulatory goals. In particular he examines the interaction between 'top-down' or traditional 'command and control' forms of regulation and the *de facto* arrangements he elucidated in the first part. As part of this discussion, Rip draws out a strand of debate that was present at a number of points in the conference, both in papers presented and attendant discussions, and which is drawn out by Van den Daele and Schellekens in their contributions: that of individual responsibility for technological development. Rip highlights the emphasis on responsible development in codes of conduct for nanotech innovation on both sides of the Atlantic. Ultimately the paper identifies a shift away from traditional governance forms and traces the outline of a new pattern emerging. Although this pattern is yet to crystallise, Rip pinpoints a key element of this overarching configuration: the discourse of anticipatory governance. This discourse anticipates from an early stage of technological development the eventual social embedding of the new technology, possible interactions between various actors within the governance process as well as responsibilities in what is by definition a de-centralised mode of governance. As such, *de facto* governance in

the sphere of nanotechnology might contain the beginnings of an intelligent response to the Collingridge dilemma.

The final paper in this section moves away from consideration of self-regulation and presents instead an institutional angle. The contribution by Nicolle Zeegers presents a considered attempt to incorporate apparently incompatible moral and religious values within regulation – in this case, legislation at the national level. As with Gavaghan's contribution, Zeegers focuses on the 2008 UK Human Fertilisation and Embryology Act; however, Zeegers examines the processes and discussions leading up to the Act, and in particular to the debate within Parliament as to whether to prohibit human-animal hybrid embryos, and within the Human Fertilisation and Embryology Agency concerning the definition of an embryo, and whether human-animal hybrids fell within it.

Zeegers explicitly takes the communicative approach as her normative starting point, noting at the outset that according communicative processes a central position in the formulation of legislation in such a sensitive area would allow for a plurality of perspectives and understandings of what constitutes an embryo to be incorporated. However, by analysing the UK debate, she concludes that the integration of alternative perspectives concerning the use of hybrid embryos in research was prevented by various power relations in the communicative process, with concerns about human-animal hybrids simply being put aside at the crucial moment of decision. What this paper ultimately does is highlight the unwillingness of the dominant (scientific) perspective to take minority views in this debate seriously and raises again the issue of the legitimacy of regulation and of those values that we label as 'fundamental' in the face of the plurality of ethical standpoints in contemporary societies.

1.6. The Multi-dimensional Discipline of Technology Regulation?

The final paper in the volume provides the core idea around which this volume has been organised, namely the vision of the discipline of technology regulation as a multi-dimensional space. The paper by Bert-Jaap Koops is both visionary and practical. Moreover, it assists us in plotting the complexity of the relationships and interactions between technology, society, politics, institutions, creativity, fear and social relationships. Although we have been able in this volume to group papers only according to one dimension, Koops's innovative approach is intended to allow us to plot complexity by reference to any number or all of the dimensions he elaborates. All of the papers brought together here could easily have been placed under other dimensional headings, and doing so would bring a different aspect of the author's viewpoint or

findings to the fore, enriching our understanding of individual contributions within the broader field. Without ruling out the possibility of a better mapping device being possible tomorrow, for now we hope to show you what a map of the discipline based upon dimensionality might look like and why it may be a useful way in which to unravel and plot the present and the future of technology regulation.

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Part 1. The Dimension of Technology Type

Chapter 2. Calculable Risks? An Analysis of the European Seveso Regime

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Abstract
The chemical sector is confronted with risks pertaining to accidents involving dangerous substances. At the European level, a set of regulations – the Seveso regime – aims at controlling such risks. This paper explores how this regime is put into practice, by analyzing the local practices of enforcement by Dutch inspectors and compliance by Dutch chemical companies. These empirical insights demonstrate that the classical 'positivistic risk paradigm' – which presents risks as calculable, controllable and reducible – seems to dominate in the Seveso regime. The analysis in this paper shows that this can lead to 'uncertainty blindness' – a regulatory regime where only yesterday's accidents are managed and salient future risks are potentially overlooked. We suggest that both regulators and regulatees should start accepting the possibility of uncertain risks, which implies a cultural change in the current regulatory regime.

2.1. Introduction

Regulation plays an important role in controlling risks. This also holds for risks associated with the chemical industry. Industrial risks are complex because within a chemical plant, the processing, storing and transport of dangerous substances involve risks, hereby creating accumulation and interplay of many risk factors. The chemical sector is confronted with the possibility of accidents involving dangerous substances. Past accidents in the chemical industry in, amongst others, Bhopal, Mexico City and Seveso have led to attempts in the European Union (EU) to control such major-accident hazards. A set of two EU directives and three amendments – together defined as the 'Seveso regime' – aims to regulate the chemical industry in order to prevent accidents. In the history of the Seveso regime, it is clear that each time a major accident happened, the rules were redefined and sharpened. It is thus assumed by the regulators that tight(er) regulation is the best way to regulate risks in the chemical industry.

In this paper we explore the local practices of Dutch companies and inspectors in applying the Seveso rules and regulations. How do the

two groups of actors involved in this regulatory regime – the regulators and the regulatees – perceive the risks at stake? Based on in-depth interviews with both parties, we will demonstrate that the classical 'positivistic risk paradigm' which presents risks as calculable, controllable and reducible seems to dominate within the Seveso regulatory regime. The Seveso definition of risk suggests a focus on simple, calculable risks at the expense of risks that are uncertain. This impression of 'uncertainty intolerance' is supported by the very detailed and complex character of the regulation, which breathes the pretence of full control and absolute safety. Two rounds of semi-structured interviews (n=17)[1] with Dutch inspectors and chemical companies provide insight into the way in which risks are perceived and regulated. Our analysis shows that the current Seveso regime – to put it somewhat provocatively – 'lags behind' new academic insights, and could even be labeled as 'uncertainty blind'. This paper concludes by stating that we are in need of a more reflexive regime in which regulators stimulate uncertainty tolerance.

2.2. The Seveso Regime

The explosion of a chemical plant in Flixborough (United Kingdom) in 1974 led to 28 fatalities. The next year, a naphtha cracker exploded in Beek (The Netherlands), killing 14 employees. A year later, two accidents occurred in Italy: one in Manfredonia and one in Seveso where a vapour cloud containing lethal dioxins escaped from a chemical plant and resulted in 2,000 people having to be treated for dioxin poisoning. While most member states of the European Union at that time had their national systems to regulate such risks, the quick succession of these accidents on European territory suggested a need for international action due to the 'dread, novelty nature and uncontrollability of the hazard' at stake (Arcuri, 2005: 207).

After three years of negotiations, the Seveso Directive was adopted in 1982. Further accidents led to amendments that broadened the scope of this first directive: the 1987 Bhopal (India) accident which caused more than 2,500 deaths led to a first amendment, and the 1988 accident in Basel (Switzerland) which caused major pollution of the Rhine triggered a second amendment. Research into registered accidents led to the 'recognition that approximately 85% of over 300 accidents reported under Seveso I have shown some deficiencies in the management system' (Porter and Wettig, 1999: 3). Therefore, a second

[1] The first round of interviews took place in 2000 (n=11; see Versluis, 2003); the second round took place in 2008 (n=6). Interviews are referred to via '#' and the interview number as listed in Annex I.

(replacing) Seveso directive was introduced that changed the scope from identifying a list of named substances and regulating individual technical installations[2] to focusing on the management systems of entire establishments.[3] The latest amendment to the directive stems from 2003; it was introduced after the accident with the fireworks storage facility in Enschede (The Netherlands) in 2000 and the explosion of a fertilizer plant in Toulouse (France) in 2001.

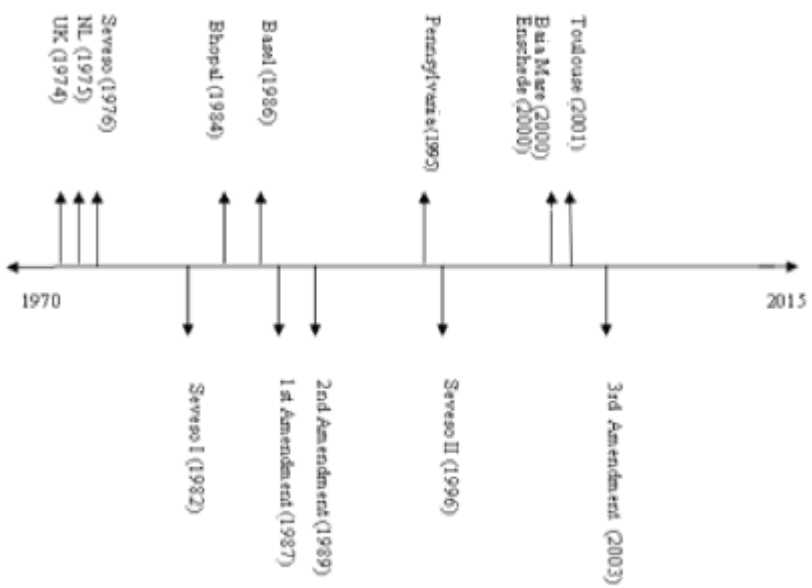

Figure 2.1: Timeline of accidents and EU regulation

Every change in the Seveso regime is a response to a major accident (see Figure 2.1). Each time, the rules have been redefined and sharpened. It is thus assumed by the regulators that tight(er) regulation is the best way to regulate risks in the chemical industry. It is to be realized, however, that each accident revealed a new risk, i.e. a possible hazard neither considered nor known from previous experience. As a representative of a chemical company stated: 'in case something new happens you get new insights' (# 5). Instead of anticipating a broad range of both known and imaginable new risks, the

[2] An installation is a 'technical unit within an establishment in which dangerous substances are produced, used, handled or stored' (Directive 96/82/EC, article 3).

[3] An establishment is the 'whole area under the control of an operator where dangerous substances are present in one or more installations' (Directive 96/82/EC, article 3).

regulators mainly seem to manage yesterday's accidents rather than tomorrow's risks.

Under this European Seveso regime, chemical companies that house a certain threshold of listed chemical substances (e.g. ammonium nitrate, hydrogen, or chlorine), are considered to be 'Seveso establishments'. They are required, firstly, to prevent major accidents from happening and, secondly, in case accidents do happen, to control the consequences for man and the environment. Seveso companies have to draw up, among other things, a 'major accident prevention policy' via a 'safety report' and internal and external 'emergency plans'. Furthermore, they have to control 'domino effects' in areas where Seveso companies are located close together, such as industry parks, and they have to alert all people liable to be affected by a major accident. Member state governments are to ensure that the risks regulated under this regime are taken into account in national land-use planning legislation, and they are to set up 'competent authorities' responsible for inspecting the regulatees. All in all, the directive asks for a considerable number of required activities from both regulators and regulatees. In this paper, we will especially analyze the regulation of risks via the safety report requirements (Directive 96/82/EC, article 9).

The Seveso regime makes use of European directives. As a directive is binding in the results to be achieved rather than in the means, all 27 EU member states first have to transpose such a directive into national legislation. Member states, in other words, have the opportunity to make the rather vague European requirements more explicit at the national level. As the Seveso directives are so-called minimum directives,[4] they furthermore allow member states to add additional requirements while transposing. How the risks are regulated precisely, in other words, is to a large extent up to the member states. EU directives only come to life in the enforcement and compliance practices at the local level. Nevertheless, the Seveso regime obviously does set the context for the local practices.

2.3. The Seveso Regime and the Positivistic Risk Paradigm

In the Seveso directive, risk is defined as the 'likelihood of a specific effect occurring within a specified period or in specified circumstances' (Directive 96/82/EC, article 3). The definition of risk in the Seveso regime resonates with the classic definition of risk as a function of

[4] Directives not based on articles 114-118 regarding the approximation of laws (Treaty Establishing the European Community) are considered to lay down minimum standards.

probability (= likelihood) and effect, which was inspired by the work of the economist Knight (1921). He argued that it is possible and necessary to distinguish sharply uncertainty from risk. He views risks as the calculable, hence controllable, islands in the sea of uncertainty (Nowotny et al., 2001). Langlois and Cosgel (1993: 3) argue that 'Knight's distinction between risk and uncertainty has been taken to differentiate between the measurability/unmeasurability of probability'. In this paradigm – also referred to as the 'positivistic risk paradigm' (Van Asselt, 2000; Krayer von Kraus et al., 2005) – risk is used to refer to hazards that are known and calculable from previous experience. Risks are thus presented as calculable and controllable.

This dichotomy is still the dominant way of looking at risk. However, an increasing number of authors (see, for example, Vercelli, 1995; Gezondheidsraad 1995, 1996; Nowotny et al., 2001; Van Asselt and Vos, 2006; Renn 2006; Renn and Walker, 2008) argue that uncertainty and risk cannot as easily be distinguished as the positivistic risk paradigm assumes. Some risks are simple, in the sense of certain enough to be calculated as a function of probability and effect. In those cases, due to past experience and the associated availability of statistical data, probability can be estimated and a measure of effect can be derived. Simple risks are calculable and relatively easy to manage. Existing risk assessment tools and risk management approaches suffice.

However, many risks are not that simple. Risk refers to potential events with consequences that one or more actors evaluated as negative. In many cases such events and/or consequences are highly uncertain, because they consider new hazards or involve situations with structural changes compared to the past. In the latter case, the available statistics are of limited value to estimate probability and effect, as the historical data no longer do justice to current and future situations. Furthermore, many risks are complex, which also contributes to uncertainty. They involve a multitude of effects, of which some may extend into the long term, that cannot be easily assessed and compared; nor can measures of effect, if available, easily be added. Risks may also involve complex causalities, non-linear relationships as well as interactions between effects. Uncertainties about the relevant phenomena and the underlying multi-causal relationships may render it difficult, if not impossible, to determine what may happen. Such risks are thus not, or at best only partly, calculable, because the probability of occurrence or the damage cannot be estimated, and even the potential hazard and the relevant causalities may not be established, although there are suspicions of danger.

Van Asselt and Vos (2006) used the notion of 'uncertain risks' to refer to risks that may be distinguished from 'safe uncertainties', as

uncertain risks pertain to uncertain situations, which may result in one or more effects that are valued negatively or considered unacceptable by at least one, but possibly more, societal actors. Renn (2006; see also Renn and Walker, 2008) proposes to further differentiate between uncertain risks, complex risks and ambiguous risks. However, as argued in Van Asselt (2000), complexity goes hand in glove with fundamental uncertainty. Although not all uncertain risks are necessarily complex, all complex risks involve uncertainty. Ambiguous risks refer to situations in which 'value judgements [about risks] (...) differ from one individual to another' (Renn and Walker, 2008: 38-40); this usually occurs in multi-actor settings. However, we would like to argue that this is not an independent category. Both simple risks and uncertain, complex risks may be laden with ambiguity, but ambiguous risks are either simple or uncertain. We would like to argue that the most important distinction is the difference between simple risks on the one hand, and uncertain risks on the other. The further differentiation into complex and ambiguous risks can be integrated in such a scheme (see figure 2.2).

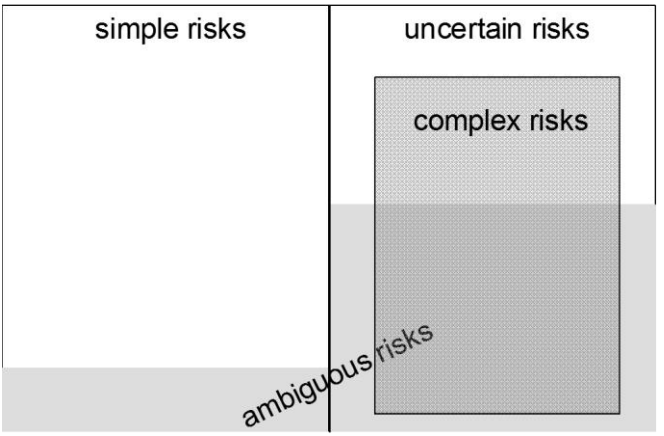

Figure 2.2: Types of risk

In the positivistic Knightian risk paradigm, uncertain, complex and/or ambiguous risks are overlooked. However, the occurrence of new hazards demonstrates the need for expanding the conceptualization of risk. The most important reason to recognize different types of risk is that different types of risk require fundamentally different assessment, management and communication approaches (e.g. Wynne, 2001; Lofstedt, 2005; Van Asselt and Vos, 2006; Renn, 2006; WRR, 2008).

The Seveso definition of risk as the 'likelihood of a specific [adverse] effect' suggests that all accident risks in the chemical sector are simple.

However, we would like to argue that major accident risks are often uncertain, complex and ambiguous (see also WRR, 2008). Risks in the chemical industry do not concern singular risks, but involve accumulation and interplay of different but correlated risk factors, as well as multiple, heterogeneous and long-term effects. For example, within a chemical plant, not only the processing installations, but also the storing facilities and transport involve interdependent risks, which need to be addressed both separately and in relation to each other. Furthermore, uncertainties about the underlying processes and the complex multi-causal relationships between causes and effects may render it difficult, if not impossible, to determine what may happen. Many actors with different perspectives (for instance, emphasizing either environmental risks, health risks or economic benefits) have a stake in the regulation of major accident risks in the chemical industry. For example, one of the interviewed companies has a pit below a weighbridge that can accommodate the complete contents of a tank-lorry. Sometimes a bit of rainwater falls into the pit:

> 'We have a level meter with a little pump connected to it, that automatically pumps away the water after it has reached a certain level. The environmental inspector argued that the pump should not work automatically because you cannot be certain what kind of liquid is in the pit. But the fire inspector said that it is important that the pump always works automatically as the risk of an overflow of liquids is too high. So these are contradictory advices' (# 2).

The Seveso directive, furthermore, involves the local, regional, national and European level. Inspection teams illustrated this by saying:

> 'You have to deal with politicians at the national and provincial level. However, my colleagues of the other inspection teams and industry also have their bosses at these levels. Thus overall, you have to deal with several political levels which complicates matters, especially when they have different priorities' (# 3).

In our interviews, spokesmen from both the inspection and industry indicated that these actors do not necessarily have contradictory goals, but the reality of the Seveso regime is a complex combination of different policy fields and of actors at different levels. This situation aggravates the problem that major accident risks are not simple and calculable. When uncertain risks, which are often also complex and/or ambiguous, are not considered, unprecedented accidents happen by surprise. The Seveso definition of risk suggests that this risk regime adheres to the positivistic risk paradigm, which implies a focus on simple, calculable risks at the expense of risks that are uncertain. Close reading of the safety report requirements provides some further support for this impression.

Annex II of the Seveso II directive specifies the minimum data to be included in a safety report. Considering the fact that safety reports produced by the chemical industry are on average 400 pages long (Versluis, 2003: 130), this one-page annex is extremely ambiguous in defining the criteria. A safety report should, amongst others, contain a 'detailed description of the possible major-accident scenarios and their probability or the conditions under which they occur including a summary of the events which may play a role in triggering each of these scenarios' (Directive 96/82/EC, Annex II). It is not specified, however, what a scenario is, what is meant by a detailed description, or what types of events are referred to. A further problem is more fundamental. In the context of risk management, scenarios are coherent descriptions of alternative hypothetical futures as an effort to capture a wide range of possible future developments and circumstances. It is possible to reason about conditions under which they may occur or the events that may trigger a scenario to unfold; however, establishing a scenario's probability, i.e. likelihood of occurrence, is difficult if not impossible. Generally speaking, there are two ways to arrive at probability estimates: 1) statistics about previous accidents are used to estimate how often such accidents occur, which is used as a basis to forecast the likelihood of such an accident in the future (this is referred to as the frequentist approach), and 2) probability is interpreted as a subjective degree of belief, which implies that expert judgements are used (this is referred to as the Bayesian approach). Especially when scenarios feature conditions or events not experienced before, the frequentist approach is not applicable; then, the question is how to value experts' degrees of belief, as research on foresight (see, for example, Van Notten, 2005) has indicated that it is difficult, also for experts, to take unprecedented scenarios seriously. In such cases, probability is solely a reflection of our experience with past accidents, and does not necessarily inform about future risks. The series of accidents that inspired the Seveso regime demonstrate that unprecedented scenarios do happen in practice, notwithstanding low probabilities.

In the positivistic risk paradigms, risks only existed when they have manifested themselves. This stimulates reactive risk regulation. So the history of the Seveso regime, i.e. changes the regulatory regime after an accident that has demonstrated the reality of a risk, provides further support for the idea that the positivistic risk paradigm frames this regime. The regulators aim to learn lessons from new accidents. However, it can be argued that an important lesson which can be drawn from the series of major accidents, i.e. the need to question the positivistic risk paradigm and to recognize uncertain risks, is not (yet) understood.

2.4. The Dutch Regulatory Practice

So far, we have examined the Seveso regime from a risk perspective through close reading of the directives and amendments. In the second part of this paper, we will investigate the practice of the Seveso regime. Informed by two rounds of interviews, we discuss Dutch regulatory practice.

2.4.1. Conceptualization of Risk

As the Seveso directive is the basis for regulation in member states, it should not come as a surprise that we encountered the positivistic risk definition also in the interviews with both the regulators and the regulatees:

> 'There are two sides to risk: chance and effect. In case of large effects within a scenario, you will work on chance calculations' (# 3; regulator).
> 'First they [risks] are quantified and then classified' (# 4; regulatee).

Recently, a further distinction has been introduced in Dutch regulation and inspection procedures. Risks are classified as controllable risks or as so-called 'leftover risks' (In Dutch: *rest-risico's*). 'Leftover risks' can be calculated, but they are either difficult to control pro-actively or pertain to too expensive, exceptional situations. One of the interviewees described leftover risks as follows:

> 'Leftover risks are an articulation of the fact that you know upfront that a certain disaster with a very small calculated chance of occurring cannot be prevented. It is a theoretical model, but there is a risk that you tolerate' (# 1).

What does this category of leftover risks, and the ways in which it is described, tell about the underlying risk assumptions? Different characteristics are ascribed to leftover risks. They are calculable, but difficult to manage or it is undesirable to manage them, because the costs of managing are either too high or disproportional compared to the (calculated) probability. So these risks are tolerated, in the sense that no risk management measures are taken to prevent or mitigate these leftover risks. With the notion 'leftover', it is communicated that these risks are unimportant from a risk-management point of view. The recognition of limits to controllability are also visible in the following interview quote:

> 'We can control the normal risks that derive from operating a chemical factory. But we do not control all risks; when a plane crashes, there is nothing I can do' (# 4; see also 5).

Although it is recognised that there are limits to controllability, neither uncertainty with regard to occurrence and effects nor ambiguity with

regard to tolerability, which is a normative notion, are considered. By presenting uncontrollable risks as 'leftover' and/or exceptional scenarios, this category is marginalized. In terms of our typology of risks, notwithstanding the distinction between controllable and leftover risk, which is a slight departure from the positivistic risk paradigm, major accident risks are still treated as calculable, simple risks.

So, we conclude that also in the Dutch practice, uncertainty is not acknowledged in the framing of risk. Risks are presented as calculable and as a function of probability and effect. Nevertheless, in a single interview, some uncertainty awareness could be sensed. For example:

> 'With some QRA [quantitative risk analysis] methods your calculations will be outdated because of the improvements that have been carried out, which makes your value unreliable' (# 3).

Here it is recognised that past data do not do justice to present and new circumstances, which have structurally changed compared to the past, in this case because of improvements at the Seveso establishment.

2.4.2 Transposition

As stated, the European Seveso regime works with directives, thereby leaving considerable freedom for the member state to shape the regulatory process. The Netherlands has used this opportunity. Transposition of the Seveso II Directive in the Netherlands took place via one act of primary legislation ('wet'), five acts of secondary legislation ('besluit') and one alternative instrument ('circulaire').[5] In comparison to other member states, this resulted in a relatively strict and detailed interpretation of the Seveso rules on paper in the transposition phase (Versluis, 2003). Especially in relation to the safety report, the Netherlands has used the right to add additional requirements. Dutch companies are required to conduct a Quantitative Risk Analysis. In such an analysis, the risks should be calculated of a loss of containment from an installation to reach beyond the fence of an establishment and damage the external environment and people outside. The Dutch government set a fixed amount referred to as the maximum acceptable risk. If the calculated risks are higher, the company will have to take more precautionary measures, or install more 'lines of defense' or 'layers of protection' as phrased in the

[5] Without taking formatting differences into account, the Dutch transposition has used comparatively much 'paper'. While the directive itself consists of 21 pages, the Spanish transposition was arranged in 14 pages, the German in 53, the British in 62 and the Dutch in 71 (Versluis, 2003: 236).

Seveso regime.[6] So, in the Dutch transposition, the calculability of risks gets even more emphasis. It does not consider the option that risks cannot be calculated and compared with a fixed number in a straightforward manner. One of the inspectors defended this positivistic framing in the following way:

> 'Companies need to depart from the assumption that you can identify and control the risks, otherwise you cannot normally operate a company' (# 6).

This can be considered a seminal example of uncertainty intolerance (see Van Asselt and Vos, 2006, 2008, for other examples of uncertainty intolerance in the context of risk regulation). Uncertainty is presented as a threat and is, in the same breath, waved aside.

At the same time, however, the notion of risk is not literally used in the Dutch legislation due to differences in points of view between two of the three ministries involved.[7] Whereas 'risk' is quantitatively measurable for the environmental ministry, it is a qualitative concept for the social affairs ministry (Versluis, 2003). So, we could argue that in the context of Seveso, the environmental ministry adheres to the positivistic risk paradigm, while the social affairs ministry questions it. The dispute was 'solved' in two ways: 1) use of the notion of 'risk' was circumvented, and 2) companies were asked to produce both quantitative risk analyses and detailed descriptions of scenarios. However, adding the explicit requirement of a Quantitative Risk Analysis actually reinforces the perception that all major accident risks are quantifiable.

2.4.3 Enforcement

As the Seveso regime combines a series of aims, more than one inspectorate is involved in its enforcement. While preventing major accidents is the primary aim, mitigating the consequences of accidents which nevertheless occur is crucial as well. The nature of the harm the directive tries to prevent – i.e. consequences for the environment, employees of companies and people in the neighbourhood – influences the inspectorates involved: the environmental inspectorate, the labor inspectorate and the fire brigade. Teams of these three agencies (usually 3 to 6 people) together assess submitted safety reports. In the first years, assessing the safety reports was very time-consuming. The main reason for this was the Dutch interpretation of the directive.

[6] These lines or layers serve to prevent an initiating event (e.g. loss of cooling) from developing into an incident (typically a release of a dangerous substance).

[7] Ministry of Housing, Spatial Planning and the Environment and Ministry of Social Affairs and Employment; the Ministry of the Interior and Kingdom Relations showed less specific interest.

Whereas the directive states that member states have to organize inspections to check whether operators can demonstrate that they have taken the appropriate measures to prevent major accidents (Directive 96/82/EC, article 18), the Dutch transposition added the requirement that the inspectors should also test the 'acceptability' of the measures. In other words, instead of 'just' assessing the safety reports, the inspectors had to approve the safety measures inscribed in the reports. For many inspectors this proved problematic due to potential problems with accountability (# 1, 3). As safety reports piled up at desks of inspectorates, it was quickly decided that the Dutch legislation should be changed in this respect. Now inspectors only have to assess the 'completeness' ('are the relevant topics documented?') and 'suitability' ('are the described measures sufficiently in line with the current technical and scientific knowledge and suitable for the situation?'). The fact that the inspectors felt uncomfortable with the responsibility for the safety measures may also be read as a sign that they realized that in the positivistic Seveso regime, uncertain risks are overlooked and that the safety measures inspired by previous accidents do not guarantee that new accidents will not happen or will be mitigated adequately. So, they did not agree with the pretence of control which would have been further strengthened by their stamp of approval.

2.4.4 Risk Calculations

The framing of risk in the Seveso regime and in the Dutch regulatory approach shapes the compliance practices among the regulatees. The decision by the Dutch government to add the requirement to conduct a Quantitative Risk Analysis determines how companies address risks. Dutch 'Seveso companies', generally speaking, calculate risks by using matrices that categorize potential hazards in terms of probability (i.e. ranging from 'occurs frequently' to 'hardly ever occurs') and calculate the possible number of fatalities or injuries (i.e. effects). These risk calculations serve as a foundation for exploring precautionary (also referred to as 'pro-active'), preventive and/or mitigating possibilities. The bow-tie approach used by one of the companies (see Figure 2.3) illustrates this approach to risk assessment and risk management. Not surprisingly, taking into account the risk framings inscribed in the Seveso regime and the Dutch transposition, the underlying framing of risk as a function of probability and effect and as a quantifiable variable can be qualified as positivistic. Again limits to controllability are recognised in the use of the so-called 'ALARP principle'. ALARP stands for As Low as Reasonably Practicable, which refers to an evaluation in terms of feasibility in view of costs and other practical constraints.

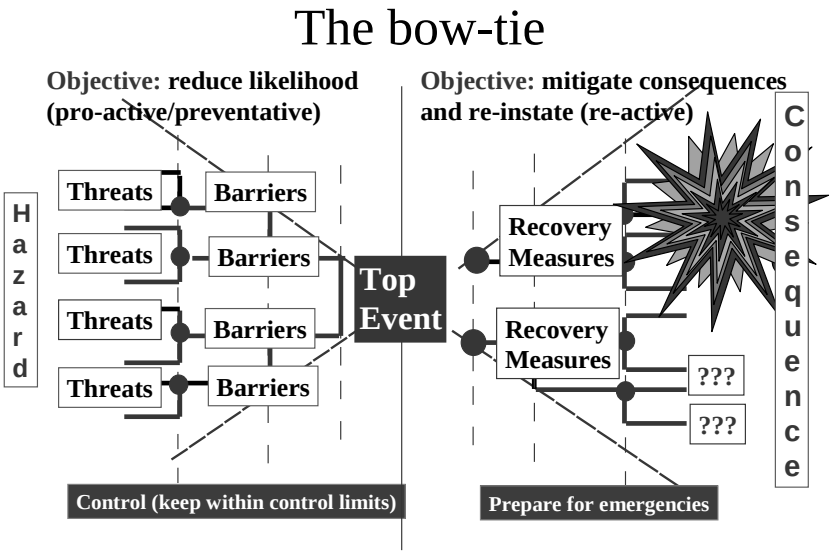

Figure 2.3: Example of a 'bow-tie'

Not only companies favor a quantitative approach. One of the companies used brainstorming with all relevant experts to identify which scenarios are most probable as a way to assess risks. Although they did accept the probability framing, their more qualitative approach was considered too subjective, according to our interviewee (# 4). It was one of the reasons that the safety report was rejected four times:

> 'They found our approach not sufficiently objective, too much "natural wit". Only when we started working with matrices scoring chance and effects for all scenarios, they found the approach acceptable' (# 4).

Overall we can thus state that despite certain exceptions – e.g. the risk notion of the social affairs ministry and the above mentioned use of the ALARP principle – the positivistic risk paradigm dominates the Dutch practice under the Seveso regime.

2.5. Conclusions and Recommendations

Our analysis has shown that the Seveso regime is strongly rooted in the positivistic risk paradigm: risks are presented as calculable and controllable. Major accident risks seem to be considered simple. The possibility of uncertain risks is overlooked, although the series of accidents that informed the Seveso regime actually demonstrate that

unprecedented scenarios, hence uncertain risks, do materialize. Although in Dutch practice some limits to controllability are recognised, the framing is still overly positivistic. Risks are calculable and should be calculated. In other risk regulatory settings, Van Asselt and Vos (2006; 2008) observed an uncertainty paradox: uncertainty about the risks concerned is acknowledged, but nevertheless the role of science and expertise is framed in terms of providing certainty. In the Seveso practice, however, generally speaking uncertainty is not even broadly acknowledged. Where Van Asselt and Vos (2006; 2008) observed how in uncertainty paradox situations, uncertainty awareness goes hand in glove with uncertainty intolerance, it seems no exaggeration to qualify the Seveso regime as 'uncertainty blind'. We have shown that this uncertainty-blind risk regime is rooted in the 'old' positivistic risk paradigm. To put it somewhat provocatively: the current Seveso regime 'lags behind' new academic insights. Is this a problem from a governance point of view?

Major accidents in the chemical industry, whether Bhopal or Enschede, demonstrate that notwithstanding the lessons learned from previous major accidents, unprecedented scenarios continued to take place in which uncertain risks materialize. It is quite unlikely that from now on managing yesterday's accidents guarantees that salient future risks are identified and controlled. Uncertainty blindness implies that neither regulators nor regulatees, let alone the public, prepare for accidents that have not happened in the past but may happen in the future. The famous risk sociologist Ulrich Beck (1986) provocatively coined the notion of 'organized irresponsibility' to describe a state of affairs in which society is unprepared for inevitable surprises, notwithstanding all institutions and procedures in place and the pretence of certainty and control. It is a too cheap shot to conclude that the Seveso regime is currently in a state of organized irresponsibility, but our analysis suggests that it is important to point out that the current institutions and procedures tend to suggest that all major accident risks are controlled, while uncertain risks are actually not attended to. A new major accident is not only a problem in terms of casualties, long-term health effects, environmental impacts, infrastructural damage and economic costs, but it also demonstrates that not all major accident risks are controlled, notwithstanding all the institutions and procedures in place. That fact may decrease trust in both the regulators and the regulatees. Lack of trust renders it even more difficult to organize responsible risk governance (Löfstedt, 2005).

So what would we recommend? We advise the actors involved in the Seveso regime to accept the possibility of uncertain risks and to accept that treating them as simple risks is like using a saw to hammer a nail. Uncertain risks cannot be calculated with traditional risk assessment

tools. With regard to uncertain risks, assessment implies sensitizing relevant actors for unprecedented scenarios. This is not a matter of methodology, but a matter of culture. The current approach invites that rules are taken for granted in a too dogmatic fashion (compare WRR, 2008). The challenge is to develop a more reflexive regime, in which the aim is not to comply with rules, but to organize safety. Alertness with regard to unprecedented scenarios may result in preventing or adequately mitigating accidents that have not happened before. One of our interviewees (# 1) used the notion of 'safety culture'. The current regime focuses on chemical risks per se, but it seems sensible to put more emphasis on assessing companies' safety cultures (see Vaughan, 1996). Key questions in such a vein would be: How is the company dealing with simple risks? Is the company uncertainty tolerant? How does the company reason about uncertain risks? What kinds of scenarios are considered? How is this reasoning translated in terms of measures, management systems and culture? The role of inspectors with regard to uncertain risks would then shift from evaluating whether the assessment is complete, to suggesting examples of uncertainties and unprecedented scenarios in order to evaluate how the company 'digests' such uncertainties and how they propose to deal with situations sketched in the scenarios. The role of the regulator would shift from trying to code all lessons from previous accidents in new rules to developing ways to stimulate uncertainty tolerance among the regulatees as well as the general public, and to finding ways to communicate about uncertain risks with the broader public. The latter is more easily said then done, but that does not imply it is not worth trying. To continue affairs as before runs the risk of deteriorating into the trap of organized irresponsibility. That is an uncertain governance risk, but one worth considering.

Annex I – Interviews

Interviews 2008

1. 13-03-2008 Environmental inspector, Rotterdam harbor area
2. 17-03-2008 Chemical company, Rotterdam harbor area
3. 18-03-2008 Senior inspector & teamleader Labor Inspectorate (joint interview), Limburg region
4. 18-03-2008 Chemical company, Limburg region
5. 01-04-2008 Chemical company, Limburg region
6. 22-05-2008 Team meeting, inspectors Labor Inspectorate and Environmental Inspectorate, Rotterdam harbor area

Interviews 2000

7. 16-12-1999 Environmental inspector, Labor inspector, representative fire brigade (joint interview), Rotterdam harbor area
8. 10-01-2000 Representative headquarter Labor inspectorate, Rotterdam harbor area
9. 10-01-2000 Two Labor inspectors (joint interview), Rotterdam harbor area
10. 03-02-2000 Representative Dutch Association for the Chemical Industry (VNCI), Leidschendam
11. 04-02-2000 Representative fire brigade, Brabant region
12. 07-02-2000 Representative Ministry of Housing, Spatial Planning and the Environment, The Hague
13. 16-02-2000 Representative Ministry of the Interior and Kingdom Relations, The Hague
14. 05-06-2000 Chemical company, Limburg region
15. 07-06-2000 Chemical company, Rotterdam harbor area
16. 08-06-2000 Chemical company, Rotterdam harbor area
17. 22-06-2000 Chemical company, Gelderland region

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Chapter 3. Facebook and the Commercialisation of Personal Information: Some Questions of Provider-to-User Privacy

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Abstract
Most of the debate about online social networking sites, such as Facebook, has thus far revolved around questions of privacy and access to personal information. Users of such services, should they choose to exercise them, have a myriad of privacy options that allow them to restrict access to their own personal information posted online, and the privacy policies of such sites are abundantly clear that the making of such choices is the responsibility of the users themselves. However, due to the focus resting upon these peer-to-peer privacy questions, those relating to the service provider-to-user relationship have been overlooked. This paper seeks to highlight some of the more subtle privacy issues of (what we will call) the 'Facebook debate' in terms of two main considerations: the access to and the control of personal information on the part of the provider.

3.1. Introduction[1]

Online social networking sites have been around since the mid-to-late 1990s,[2] but only in the past few years has the 'craze' really entered the mainstream[3] in the shape of MySpace, Friendster, Bebo, Hi5 and, particularly, Facebook.[4] Some sites have a specific intended purpose,

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[1] This paper was presented at the *TILTing* Perspectives *on Regulating Technologies* conference, hosted by the Tilburg Institute for Law, Technology, and Society, Tilburg University, Netherlands, in December 2008. An earlier version of this paper was presented at the BILETA Annual Conference on 'Law Shaping Technology, Technology Shaping the Law', held at Glasgow's Caledonian University in March 2008. Our thanks go to Elaine Sutherland, Fraser Davidson, Rosa Greaves, Alison Green, Richard Jones, Elizabeth Crawford and Janeen Carruthers for their suggestions and comments. Any errors, of course, remain our own.

[2] Early examples include Classmates.com, which started in 1995 and focused on connecting former school friends, and SixDegrees.com, which started in 1997 but closed in 2000 after 'struggling to find a purpose for its concept' of forming indirect ties. See Janelle Brown, 'Six degrees to nowhere', 21 September 1998, http://archive.salon.com/21st/reviews /1998/09/21review.html (accessed 26 February 2010).

[3] Nicole Martin, 'Debrett's guide to online etiquette', *Telegraph*, 13 June 2008, http://www.telegraph.co.uk/digitallife/main.jhtml?xml=/connected/2008/06/12/dldebretts.xml (accessed 26 February 2010).

[4] See http://www.myspace.com; http://www.friendster.com; http://www.bebo.com; http://www.Hi5.com; http://www.facebook.com (accessed 26 February 2010).

such as dating or job searches, but all of them have online communication and social interaction as their basic aim, and most share certain core features: users create a 'profile', which takes the form of a template that can be completed with personal information, including photographs, videos, preferences and opinions, and this profile can be perused or linked to by other users on the network, be they friends, former classmates, colleagues, or even perfect strangers. The personal information on a user's profile is all voluntarily 'uploaded', usually in terms of category-based representations of general interests, such as a person's musical or sporting preferences, but also personal details such as sexual orientation, religious and political views, and personal data like birthdates, phone numbers and addresses.

Due to the personal nature of this information, concerns have been raised regarding privacy, and many of the online social networking (OSN) sites listed above provide privacy controls so that users can choose both who can see their profile[5] and how much any category of 'friend' can access within that profile. However, although these privacy controls are useful in terms of restricting the access to a personal profile by other users of the social network sites (i.e. peer-to-peer access), there are few, if any, restrictions upon the service provider, namely the sites themselves, regarding the private information of the service users.

Much of the literature on this topic revolves around questions of peer-to-peer privacy and attempts to understand certain behavioural forms of information revelation, and it is not our intention here to enter into either of those debates. Rather, our focus is on the frequently overlooked issue of the service provider-to-user relationship, and the privacy questions arising from it. Instead of being purely about access to personal information, therefore, we look at the subsequent use and control of the information posted on a social networking site such as Facebook[6] by the site provider itself.

[5] Such as the 'request' and 'confirm' functions – a user wishing to be 'friends' with another user, i.e. wishing to be granted access to that individual's profile, must first request it and wait for confirmation. The recipient must either confirm or ignore this request, with access only being granted in the event of the former. Obviously this system depends upon the personal privacy settings of each user – requesting access is only an issue if it has been previously restricted in some way.

[6] There are differences across the various sites and so, for the sake of clarity, this chapter will take the Facebook site as its main focus.

3.2. Access and Control

The two issues of access and control are closely interrelated, especially in today's digital age, when duplicates are often a simple mouse-click away and dissemination of these is equally straightforward. The Internet, more than any other medium, provides a means of putting information directly into the public domain: instead of students and young people setting up pirate radio stations and crying 'reclaim the airwaves' in an attempt to be heard, the current youth generation are able, like no other before them, to disseminate information by means of social networking sites, blogs, and personal homepages. However, once information has been posted online and thus made public, it then becomes difficult for the owner or poster to control – a situation that has resulted in such Internet phenomena as the Star Wars Kid[7] and the 'Numa Numa' Dance's Gary Brolsma,[8] neither of whom were particularly happy about their unexpected infamy.

Although such phenomena are rare, and neither of the abovementioned examples had any privacy restrictions on these videos, it is evidently important to consider how and to what extent information being posted can be controlled by the owner and/or poster, and that questions relating to controlling the dissemination of information will inevitably involve considerations of access to that information. This intertwining of access and control means that concerns quickly shift from being purely about privacy to also being about (i) property, specifically intellectual property, and (ii) exploitation of private information, personal preferences and online activities by, for example, highly-targeted advertising.[9] This paper will, firstly, look at both of these examples of commoditisation of essentially private user-content and

[7] The Star Wars Kid, otherwise known as Ghyslain Raza, earned his moniker when a 2002 video he had filmed of himself swinging a golf club around his head as if it were a lightsabre(in the style of Darth Maul from the Star Wars movie) was 'shared' by a friend of his on the Kazaa peer-to-peer network. It was then adapted to include music and sound effects and, as of November 27, 2006, it was estimated to have been viewed 900 million times, making it the most popular viral video on the Internet. See http://news.bbc.co.uk/1/hi/entertainment/6187554.stm (accessed 26 February 2010).

[8] In 2004, Brolsma filmed himself on a webcam although dancing exuberantly to the pop song 'Dragostea din tei' as performed by Moldovan pop band O-Zone. With 700 million views, it comes second only to the Star Wars Kid (above). See ibid.

[9] This distinction follows that discussed by Corien Prins, who suggests that the two are conceptually separate: 'At first sight, privacy and property seem mutually exclusive concepts. [...] Some, however, argue that privacy protection on the one hand and personal data protection on the other have evolved into two highly distinct concepts'. See C. Prins, 'When Personal Data, Behaviour & Virtual Identities Become A Commodity: Would A Property Rights Approach Matter?', 3 *SCRIPT-ed* (2006) 270-303 at 275.

information, then outline some of the legal problems that exist as a result of the broad licence signed by each user on joining Facebook, before finally suggesting some possible solutions.

3.3. User Content and Intellectual Property

What does the Facebook privacy policy and its terms and conditions have to do with considerations of intellectual property? Before attempting to answer this question, it is necessary, first of all, to establish what an intellectual property right means, and in what relevant situations such a right will arise.

An intellectual property right can be defined as a right: (i) that can be treated as property; (ii) to control particular uses; (iii) of a specific type of intangible asset; and are normally characterised by (i) only being granted when the intangible asset can be attributed to an individual creator or group of creators, and (ii) being enforceable by both the civil and criminal law.[10] The legal right created gives the owner of the intellectual property 'an open-ended set of use-privileges, control powers and powers of transmission'.[11] It is this notion of control of the asset that is so important in the instance of online posting, mainly due to the fact that a Facebook user *relinquishes control* of information and 'content' posted on their profile or on the site in general (i.e. on the profile pages of others, on group pages, and on various applications[12]). The next section will explore in detail what can probably be referred to as the most commonly experienced and widely recognised issue relating to controlling personal information posted online – specifically, photographs.[13]

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[10] M. Spence (2007), *Intellectual Property*, Clarendon, OUP: Oxford, 12-13.

[11] Ibid, 15.

[12] The term 'application' applies to additional, normally (third-party) user-created, programmes that run off the site platform. At the time of writing, there were over 500,000 applications available on the Facebook website, ranging from ones that allow users to add music, videos, literary and popular culture preferences to their profiles, to ones that pinpoint a user's geographical location, allow filesharing or promote certain causes. The specific privacy implications of 'adding' an application to your profile are also not straightforward – a user must deliberately re-set their privacy options, as the default setting is to 'public' access.

[13] Groups existing within the Facebook network, such as 'My photos are MINE! NOT Facebook's! Change the Terms and conditions!' and 'Facebook: Do not sell my private pictures! Change your terms of use, NOW!' show that users are well aware of the implications of the Terms & Conditions. See: http://www.facebook.com/group.php?gid=5606823556 and http://www.facebook.com/ group.php?gid=5841663547 (accessed 26 February 2010).

3.4. Facebook Photos: Why All the Fuss?[14]

A friend of ours is camera-shy, and constantly protests that he does not want any pictures of himself 'posted' online,[15] no matter they are only accessible by friends and friends of friends. Justifications for posting photos tend to follow along the lines of 'relax, it's only friends who can see it', or 'it's a group picture, I can't take you out of it', and even 'well, I won't tag you and then it won't show up on your profile page, only on mine'.[16] Our dissatisfied and increasingly disgruntled friend points out that he is not a Facebook user and thus is not aware of pictures of him being posted, let alone which ones and by whom, and also that it matters little whether they are on one person's profile page or another – they are available and accessible online either way. That he has never given any permission for either his name or image to be used is a source of frustration for him, as he feels that he has no control of either. Imagine his horror, then, if he were to read the 'Statement of Rights and Responsibilities' that his friends are agreeing to when they post pictures on the Facebook site. According to these, by posting their 'Content' to any part of the site, users effectively grant to Facebook:

> a non-exclusive, transferable, sub-licensable, royalty-free, worldwide license to use any IP content that you post on or in connection with Facebook ("IP License").[17]

'Use' is far from the mere hosting that the uninformed reader might foresee. Only near the very end of the Statement might the reader discover that it means 'use, copy, publicly perform or display, distribute, modify, translate, and create derivative works of' and as we will see it would be an unusually unsociable user if all their content was kept so close to their chest that Facebook alone would have the right of 'use'.

In response to complaints in an earlier version of these terms which stated that the licence was 'perpetual' and 'irrevocable'[18], Facebook adds that the 'IP License ends when you delete your IP content or your account unless your content has been shared with others, and they

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[14] Photographs are by far the clearest example, which is why it has been selected here. However, text-based content such as poems, short stories, academic work – in short, anything 'post-able' to which copyright could apply – would also come under this ambit.

[15] 'Posted online' means uploaded to the internet.

[16] To 'tag' someone is to put their name on their image in a photograph, which has the effect of creating a direct link between the photograph and that person's profile page, assuming that they are a user of the site.

[17] Facebook's Statement of Rights and Responsibilities, version last revised 21 December 2009.

[18] Facebook's previous Terms of Use (accessed 7 June 2008).

have not deleted it.' This sounds comforting if the reader is unaware that the default option they will be given, of 'deactivating' their account, is not the same as deleting it. The reader is likely also to be unaware that 'sharing with others' does not refer only to the information they thought they had made publicly available – of which again, more later.

> Furthermore, Facebook's previous Terms of Use stated that:
> [Facebook reserves] the right, at our sole discretion, to change, modify, add, or delete portions of these Terms of Use at any time without further notice. If we do this, we will post the changes to these Terms of Use on this page and will indicate at the top of this page the date these terms were last revised. Your continued use of the Service or the Site after any such changes constitutes your acceptance of the new Terms of Use.

This last part was particularly interesting given the US decision in *Douglas* v *US District Court*[19] that a service provider cannot change the terms of its service contract merely by posting a revised contract on its website. It may be that *Douglas* can be distinguished on the grounds that the core activity of Facebook users involves accessing the website; however, the Court of Appeals did observe that '[p]arties to a contract have no obligation to check the terms on a periodic basis to learn whether they have been changed by the other side.'[20] Furthermore, Lemley has argued that US courts have tended not to enforce similarly restrictive 'browse-wrap' licences (in software marketing) against the consumer unless that consumer is a 'sophisticated economic entity'.[21]

> The new version seems not much better for the user, though:
> We can change this Statement if we provide you notice (by posting the change on the Facebook Site Governance Page) and an opportunity to comment To get notice of any future changes to this Statement, visit our Facebook Site Governance Page and become a fan.
>
> [but it bafflingly adds:]
>
> We can make changes for legal or administrative reasons upon notice without opportunity to comment.

Douglas aside, though, the implication of the Statement is that user Content, be it photographs, pictures, written notes, stories or any other personal information, is available to Facebook or its application

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[19] *Douglas* v *US District Court*, 495 F.3d. 1062 (9th Cir. 2007). Following appeal to the US Supreme Court, certiorari was denied: *Talk America, Inc.* v *Douglas*, 128 S.Ct. 1472 (2008).

[20] *Douglas* v *US District court,* ibid., 1066.

[21] Mark A. Lemley 'Terms of Use' 91 *Minnesota Law Review* (2006-2007), 460, 462-463. See also Dale Clapperton and Stephen Corones 'Unfair terms in 'clickwrap' and other electronic contracts' 35 *Australian Business Law Review* (2007), 152.

developers to use in any way they choose, even for commercial purposes. As we will show, exercising a supposed privacy option does not fully protect against this. To put this in the strongest light, there is the very real (albeit unlikely) possibility that our camera-shy friend could be walking down the high street one day and discover his own face staring back at him from an advertising billboard.[22] His first post-tantrum reaction would certainly be to confront the friend whose photograph it was, but to no avail – under this Statement, Facebook does not even have to ask the user's permission before making use of any posted Content which has not specifically been protected by means of the user manually overriding the publicity default. Indeed, the above-quoted licence is so comprehensive that it effectively undermines the following assertion in the Statement, which provides that:

> You own all of the content and information you post on Facebook, and you can control how it is shared ...[23]

This provision regarding ownership is, in essence, almost entirely worthless due to the scope of the licence – although the user may own all of the Content they post on the site, Facebook does not, in fact, need to own the information because they are licensed to utilise it in whichever way they choose, regardless of ownership. It is like borrowing your parents' car – at no point do you ever claim to own it, but that does not really matter when you are driving around town.

There are two separate issues relating to both privacy and property that should be considered here. These are probably best distinguished in terms of active and passive posting; the former being when a user posts a picture that they (alone) own, the latter being when a picture is posted that shows another person or group of people, to which the user does not have exclusive rights. In the Intellectual Property help section, a Facebook user is told that they 'may only upload content to the Facebook website if you are certain that you have the legal right to do so. If you are not certain that you are legally authorised to use the content you have uploaded to our website, you should remove it immediately.'[24] This gives rise to considerations of copyright, for who owns and has the right to distribute photos? Is it the photographer?

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[22] This may sound farfetched, but cases such as that of Alison Chang, a 15-year-old who saw a photo of herself, initially posted on Flickr, on an Australian Virgin Mobile advertisement, suggest that 'corporate photonapping' is a very real danger. See Monica Hesse 'Hey, Isn't That...' (9 January 2008) *Washington Post* and also: http://www.theregister. co.uk/2007/09/24/creative_commons_deception/ (accessed 26 February 2010).

[23] Statement of Rights and Responsibilities, *supra* note 17.

[24] http://www.facebook.com/album.php?aid=14347&id=635057322&saved #!/help/?page=439

The subject or subjects? What about the artist, designer, or employer? All of the above? The answer is not especially straightforward, even leaving jurisdictional concerns aside for the moment.[25]

In the UK and in terms of photographs[26] taken after 1 August 1989, generally the 'author' of a photograph is the first owner of copyright,[27] meaning that you are the owner of the copyright of any photos you take. However, this may not be the case if someone else decided on the specifics of the photograph, such as the exposure or angle, for example, or even if the people either taking or designing the photo were simply employed to do so – in this situation the employer would be the first owner. If there happens to be more than one person involved in taking, making and designing the photo, and those contributions are indistinct, then each person will be both a joint author and thus a joint owner of copyright, meaning that any usage must be unanimously agreed to.[28] This is complicated all the more by provisions on 'fair dealing',[29] which allow photographs to be used without permission providing that they are being used for specific purposes, including: non-commercial research and private study,[30] criticism and review, and where there is sufficient acknowledgement.

These copyright concerns appear to be moot, however, considering that the approach taken by Facebook here is one that, first of all and as noted above, never makes any claim to having ownership and thus any restricted rights over the photograph but rather relies upon the licence granted by the user and, secondly, rests all responsibility of actually

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[25] A notoriously complex area of law, the international copyright system can nonetheless be said to have three main rules of thumb: (i) the law of the country of origin of the work is likely to be relevant when determining ownership of copyright or authorship; (ii) the law where the infringement takes place is likely to be relevant to questions regarding the infringement, and; (iii) which courts will deal with the resolution of any international dispute will be determined with reference to international conventions on jurisdiction. As yet there are no dedicated rules governing cyberspace. See S. Stokes, *Digital Copyright: Law & Practice* (Oxford, Portland: Hart Publishing 2005), 7 and, for more detail, P. Goldstein, *International Copyright: Principles, Law & Practice* (New York: OUP 2007).

[26] The Copyright, Designs & Patents Act (CDPA) 1988, s. 4(2) defines a photograph as 'a recording of light or other radiation on any medium on which an image is produced or from which an image may by any means be produced, and which is not part of a film'.

[27] Copyright, it should be noted here, simply protects against copying and dealing in illegal copies.

[28] Intellectual Property Office, http://www.ipo.gov.uk/copy/c-applies/c-photo/c-photo-ownpost89.htm (accessed 30 January 2008).

[29] These 'fair dealing' provisions are a UK exception (Art. 5) from EC Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society of 22 May 2001. The US defence of 'fair use' is much broader in scope, as it is not limited to specific purposes; see s. 107, US Copyright Act 1976.

[30] S. 29, CDPA.

ascertaining copyright ownership with the user.[31] The user is told on the Intellectual Property page:

> '[j]ust because you have recorded content onto your own recording device, this does not necessarily mean that you own the copyright to that material or that you are authorised to use it. Disclaiming ownership of that content cannot protect you from infringing on the true owner's copyright. If you have any question whatsoever as to whether you are legally authorised to post any content, consult an attorney before uploading it to the Facebook website'.

A later question-and-answer states:

> 'How does Facebook prevent users from uploading material that is copyright infringing?
> The material uploaded to the Facebook website is uploaded by our users. Our Terms of Use prohibit users from posting content that violates another party's intellectual property rights. We encourage our users to report instances of copyright infringement using the procedures outlined in our How to Report Claims of Intellectual Property Infringement page, and we terminate the accounts of repeat infringers in appropriate circumstances.'

By requiring the user to accept their right to post the photograph in advance of doing so, Facebook thus effectively side-step any potential liability for copyright violations, although, as third party rights in copyright are not affected by the Statement, if the user is not the copyright owner then their implicit licensing of Facebook would mean little were the *true* copyright owner to bring suit.[32] Nevertheless, a peeved 'friend' whose picture has been posted by another user (passive posting) appears to have no direct recourse against Facebook, even if they subsequently have used, copied, publicly displayed or distributed it – the only option for the aggrieved party would be to take up the matter at the source, namely the original infringement. What remains unclear is whether or not 'corporate photonapping' as in the case of Alison Chang[33] would be actionable if the photograph used had been posted on Facebook, although the outcome of this hypothetical situation

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[31] The Facebook Statement further says: 'If anyone brings a claim against us related to your actions, content or information on Facebook, you will indemnify and hold us harmless from and against all damages, losses, and expenses of any kind (including reasonable legal fees and costs) related to such claim.'

[32] An important issue in this respect is whether the User in fact has the right to grant that licence – despite the requirement of 'ticking the box' it is evident that many Users simply do this as a matter of course, regardless of whether they have this right or not. If it transpires that the User does not have the authority, then any subsequent use of the material by Facebook may constitute an infringement, with the possibility of the User being secondarily liable for Facebook's infringement.

[33] As discussed above, see *supra* note 20.

would surely turn on the extent of Facebook's own involvement in the transaction: if the corporation had unilaterally copied and then used a posted photograph for commercial purposes without the express permission of either Facebook or the copyright owner, then this would appear to be an infringement.

Perhaps the most interesting observation here is that it is the users and the bloggers – 'communit[ies] typically associated with piracy' – who are now 'rallying in support of copyright'.[34] As Lawrence Lessig observes, 'average individuals are increasingly thinking of themselves as artists, whose work has value – or at least deserves respect'[35] and, although we would agree with this assertion, we would also argue that the Facebook debate is still less a commercial than a privacy concern in this respect. Commercial considerations come much more to the fore when the focus shifts from questions of (intellectual) property to those of personal information and private data.

3.5. 'Facebook Ads' – The Conundrum of Targeted Advertising

Targeted advertising is not a new phenomenon and is, indeed, one of the reasons that free-to-use websites such as Facebook, Google and MSN's Hotmail have become so lucrative. Users of Google's web-based Gmail service may have had the rather creepy experience of noticing that the little adverts beside their email seem coincidentally similar to the content of their emails. This is not coincidental: Google actually scans the text of all emails and links it to commercial advertisements, which in turn have text links displayed beside the user's inbox. This process takes place automatically and no data – not even aggregate data on the number of advertisements shown in Gmail – is relayed back to the advertiser.[36] Facebook takes a similar approach with the imaginatively-named 'Facebook Ads', a facility launched in November 2007,[37] and whose tripartite approach provides businesses with a simply staggering insight into what users and their 'friends' are interested in and are buying.

The sort of personal data provided freely by users is a hugely valuable resource for commercial profiling. Facebook's standard page layout encourages users to upload details of their favourite books, music, hobbies and interests, their political and religious affiliations, their family and relationship status, their employment circumstances, date of birth, address and other contact details, their connections with other

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[34] Lawrence Lessig, quoted by Monica Hesse, see *supra* note 20.

[35] Ibid.

[36] http://mail.google.com/mail/help/intl/en/privacy.html (accessed 26 February 2010).

[37] http://www.facebook.com/press/releases.php?p=9176 (accessed 26 February 2010).

Facebook users (who are also profiled in this manner), and much else; the structure of the pages even facilitates this self-categorising by providing a pre-set selection of categories. The value of this pre-categorised data for marketing analysis is obvious, and Facebook allows marketers to access much of it so they can create 'SocialAds'[38] targeted to the individual user.

This situation is made even more intriguing when we consider that one of Facebook's core 'principles' is 'ownership and control of information'.[39] Its introductory 'guide to privacy on Facebook' announces that 'You should have control over what you share. (...) Your privacy settings should be simple and easy to understand.'[40] Its Privacy Policy begins by avowing that 'We want to earn your trust by being transparent about how Facebook works.[41] The underlying message here is that you, the user, should be able to control who has access to your information, which in turn suggests that you control what will be done with said information. These controls take the form of optional privacy restrictions that each user can set to their own desired levels: for example, a user can opt to have their profile completely visible to all other users (standing somewhere in the region of 300 million worldwide visiting the Site each month[42]), to those who are in the same networks, or to just their 'friends' (although note that even this is not full cloaking[43]), with the further option of hiding certain information from some friends by only granting them access to your 'limited profile'.

However, and this appears to be the crucial point, these privacy controls *only apply to other users and not to Facebook itself*. Any control that the user has only relates to the access they grant (or do not grant) to other users in a peer-to-peer relationship, although the relationship of service provider-to-user stays out of the limelight. The conscious frame is the individual 'other'. Indeed, when Facebook rolled out its Social Ads, what it was telling its potential advertisers reads rather differently from what it was telling its users – for example:

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38 http://www.facebook.com/business/?socialads (accessed 26 February 2010).

39 Facebook Principles, accessed 26 February 2010.

40 http://www.facebook.com/privacy/explanation.php (accessed 26 February 2010).

41 Facebook's Privacy Policy, version 9 December 2009.

42 Eric Eldon, http://www.insidefacebook.com/2009/09/15/facebook-reaches-300-million-monthly-active-users/ (accessed 26 February 2010). Note that by this Facebook means 'monthly uniques', that is, individuals distinguished by unique identifiers such as IP code.

43 Facebook's Privacy Policy, *supra* note 39: 'Certain categories of information such as your name, profile photo, list of friends and pages you are a fan of, gender, and networks you belong to are considered publicly available, and therefore do not have privacy settings.'

> With Facebook Insights, you have access to data on activity, fan demographics, ad performance, and trends. With this information, you are better equipped to improve your custom content on Facebook and adjust your ad targeting. (...) Facebook's robust database of authentic demographic information provides you with a deep understanding of exactly who is engaging with your business and how. (...) Facebook Insights helps you learn more about your target audience.[44]

Much more disturbing from a privacy perspective, however, are the third-party applications that are given access to user data through the Facebook platform. A host of quirky and humorous applications are available to Facebook users and are part of the charm of socialising on the site. Users can display clips of their favourite films to friends, send imaginary drinks, take part in jokey quizzes, place virtual bets – the options are as wide as the developers' imaginations, and the applications are hugely popular. The default for signing up, however, is that users often give the application access to all their personal data, even if the individual's profile is otherwise set as 'private'. They may not be able to add the application if they refuse. In a 2007 survey of the top 150 applications, researcher Adrienne Felt found that 90.7% were being given more access to information than they needed to provide their service.[45] For a chilling list of what information the user gives away without explicitly being asked, see Facebook's own page giving some insight into the security gaping hole of its Platform 'service'.[46]

It comes as no surprise that in 2008 Facebook announced plans to develop an e-commerce facility to allow financial transactions to take place through the applications.[47] The site now enables apparently trivial financial transactions through a virtual currency called 'Facebook credits' such as the buying of virtual flowers for a nominal sum as 'gifts' for friends. These credits can be bought in the real currency of dollars and can for instance be paid for by being added to a mobile phone bill. Thus there already exists the (code) facility to enable companies with access to target information such as this, to sell easily to users *at the point of* use.[48]

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[44] See cached page at: http://web.archive.org/web/20080213223005/http://www.facebook.com/business/?insights, stored on 13 February 2008.

[45] http://www.cs.virginia.edu/felt/privacy/ (accessed 26 February 2010).

[46] http://developers.facebook.com/about_platform.php (accessed 26 February 2010).

[47] http://blog.washingtonpost.com/posttech/2008/06/ecommerce_on_facebook.html?nav=rss_blog (accessed 26 February 2010).

[48] The much-criticised Beacon application, which was applied to some accounts without the users' explicit consent, and which advertised to their Friends what purchases they had made on partner sites such as Amazon, was an obvious precursor of this sort of data-mining and marketing. It is now being discontinued following settlement of a legal

As we mentioned above, the casual reader of the Facebook Statement and guide to privacy may gain the misleading impression that their privacy is secure. The reader must turn to the full privacy policy to uncover the disturbing news that '[t]his privacy policy covers all of Facebook. It does not, however, apply to entities that Facebook does not own or control, such as Facebook-enhanced applications and websites' and it is only on more in-depth perusal of these documents that the reader can discover that Facebook may draw on any information in their user profile for the use of third parties; that Facebook may also use user information that it has gleaned from other sources, such as newspapers, blogs or instant messaging programs; and that Facebook may share the user's 'customer information' with other companies in connection with the user's use of a store or service that the company also happens to provide on Facebook. The Privacy Policy maintains that 'sensitive' information is encrypted; however, by this it means data such as credit card details, and not date of birth, sexual orientation or religious beliefs, which, although more mundane, are most certainly deemed 'sensitive' under the UK Data Protection Act 1998 and the European data protection directive (95/46/EC).[49]

Facebook's approach to privacy last year became the subject of a complaint to the Canadian Privacy Commissioner,[50] much of which was upheld.[51] A Canadian legal clinic based at the University of Ottawa argued that Facebook is violating several principles of the Personal Information Protection and Electronic Documents Act. Although not singling out Facebook as the sole miscreant among social networking sites, the clinic chose it for this first complaint because of its popularity.[52] The Canadian Internet Policy and Public Interest Clinic (CIPPIC) focused among other things on the typical defaults in user agreements for downloading third-party applications. CIPPIC also maintained that Facebook 'misrepresents itself as solely a social networking site',[53] failing to make it clear to users the purposes for which Facebook allows third-party developers to access personal information.

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action against Facebook: see *Lane et al* v *Facebook, Inc. et al*, Case No. 5:08-CV-03845-RS.

[49] See s. 2 and Schedule 3 Data Protection Act 1998; also see the Data Protection (Processing of Sensitive Personal Data) Order 2000, SI 2000/417.

[50] http://www.cippic.ca/uploads/CIPPICFacebookComplaint_29May08.pdf (accessed 26 February 2010).

[51] http://www.priv.gc.ca/cf-dc/2009/2009_008_0716_e.cfm (accessed 26 February 2010).

[52] http://www.cippic.ca/uploads/NewsRelease_30May08.pdf (accessed 26 February 2010).

[53] See p. 31 of the complaint, *supra* note 50. See also pp. 19-20.

The report from the Canadian Office of the Privacy Commissioner[54] made many criticisms of Facebook's policies, but one criticism is worth quoting in full:

> 'Another consent-related concern that I have is the fact that no specific consent is sought from users for the disclosure of their personal information to applications when their friends and fellow network members add applications. Facebook maintains that, through its privacy settings, users have an extensive ability to choose whether or not they will interact with any particular Facebook application and to block any particular application and opt-out of all Facebook applications in a simple way. However true this statement may be in theory, I would note that users' "ability to choose" would depend on their being knowledgeable about developers' practice of accessing and using third-party information when friends add applications. I would also note that the only way users can control the exposure of their personal information to application developers when their friends and fellow network members add applications is either to opt out of all applications altogether or to block specific applications. Moreover, the latter option would effectively require them to guess which of the more than 350,000 applications their friends and fellow network members are likely to add.
>
> I do not consider it appropriate for Facebook to put on users the onus of informing themselves and opting out of the disclosure of their personal information when friends and fellow network members add applications. Nor do I believe that the practice meets the reasonable expectations of users.'[55]

3.6. Cyberspace and Problems of Legal Challenge

In the early days of Facebook the legal reader might have wondered whether there really was an enforceable contract, particularly under English law. What economic exchange was taking place? With the advent of e-commerce on Facebook allied to the dispersal of personal data to third-party developers, the value of the licence of the user's intellectual property rights has become more obvious. Perhaps, then, such legal protections as the Unfair Contract Terms Act 1977, the Unfair Contract Terms Directive,[56] the Data Protection Act 1998 (the

[54] Elizabeth Denham, Assistant Privacy Commissioner of Canada, Report of Findings into the Complaint Filed by the Canadian Internet Policy and Public Interest Clinic (CIPPIC) against Facebook Inc. under the *Personal Information Protection and Electronic Documents Act*, 2009.

[55] Ibid., paragraphs 308-309.

[56] Implemented in the UK by the Unfair Terms in Consumer Contracts Regulations 1999.

1998 Act) or the data protection directives[57] will come into play at this point. A standard form contract that leads users into a relationship from which it is extremely difficult to extract themselves may be in practice both unreasonable and in breach of the fifth data protection principle on keeping data longer than is necessary[58] – indeed, the UK Information Commissioner investigated just such a complaint against Facebook as regards the difficulty (at the time of complaint) of removing personal data from an established account.[59]

One can also question the very need for Facebook to retain in-depth user data for any length of time. Under the second and third data protection principles, personal data can be obtained only for specified purposes and should not exceed what is needed for those purposes.[60] Although the Regulation of Investigatory Powers Act 2000 mandates that communications data be retained, it only requires this of the Internet Service Provider (ISP) and not of a social network provider.[61] In addition, a 'data subject' under the 1998 Act (which would certainly cover a Facebook user)[62] has the right under s. 10 to object to and prevent the processing of information held about them if it is likely to cause them substantial damage or distress. They also have the right under s. 7 to know what data is held on them, which would mean that, if a user leaves Facebook, they would have the right to be informed as to exactly what data remained, even in archives. In a similar vein, and considering that the right to share sensitive data requires explicit and informed consent, the default opt-out system provided by Facebook would fall short of this requirement, especially where subsequent actions by the user can have the effect of overriding the user's prior selection of an overall 'privacy' setting. However, a platform site such

[57] See the Data Protection Directive (95/46/EC) and the Directive on privacy and electronic communications (2002/58/EC).

[58] 'Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.' Part I of Schedule 1, Data Protection Act 1998.

[59] http://news.bbc.co.uk/1/hi/technology/7196803.stm (accessed 26 February 2010). See also *infra*, section 3.7.

[60] '2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.' Part I of Schedule 1, Data Protection Act 1998.

[61] Facebook only really need to keep records that meet the standards required to serve the normal purposes of the ordinary criminal law. The licence will be discussed in the next section.

[62] See s. 1(1) of the 1998 Act, which defines a 'data subject' as simply 'an individual who is the subject of personal data'.

as Facebook is able to upload all user data onto servers in the United States, thus bypassing British and EU data protection provisions (although we should emphasise that Facebook itself does in fact have a London office at present and has signed up to both the EU Safe Harbor Privacy Framework and TRUSTe dispute resolution).[63] And although a user may assume that they are governed by the law of their local jurisdiction, including rules regarding parity and fairness in contract, Facebook's Statement requires them to consent to quite another arrangement:

> You will resolve any claim, cause of action or dispute ("claim") you have with us arising out of or relating to this Statement or Facebook exclusively in a state or federal court located in Santa Clara County. The laws of the State of California will govern this Statement, as well as any claim that might arise between you and us, without regard to conflict of law provisions. You agree to submit to the personal jurisdiction of the courts located in Santa Clara County, California for the purpose of litigating all such claims.

This in practice is a significant improvement on the previous Terms of Use, which bound the User to the laws of Delaware, a much less amenable jurisdiction. However, it nonetheless raises several questions, the foremost of which relates to the very validity of such a licence.[64] In the UK, Regulation 9 of the Unfair Terms in Consumer Contracts Regulations 1999[65] prohibits exclusion by choice of law clause. Regulation 5(1) provides that '[a] contractual term which has not been individually negotiated shall be regarded as unfair if, contrary to the requirement of good faith, it causes a significant imbalance in the parties' rights and obligations arising under the contract, to the detriment of the consumer.' The Regulations cover a wider range of unfair clauses than the Unfair Contract Terms Act 1977 does and although Facebook's service is not typical of those envisaged by the drafters, it is a service with commercial implications and, as we later discuss, Facebook has recently announced plans to develop e-

[63] The 'Safe Harbour' agreement between the US and the UK was intended to provide a framework for firms in the face of different private sector data protection standards between the two areas. For more on this see, for example, A. Busch, 'From Safe Harbour to the Rough Sea? Privacy Disputes Across the Atlantic' (2006) 3 *SCRIPTed* (4) 304-321.

[64] Compulsory arbitration clauses are always treated as unfair, and exclusive jurisdiction clauses are likely to be treated as unfair, where they are governed by the Unfair Terms in Consumer Contracts Regulations 1999. For discussion of US case law on the question of mandatory arbitration clauses and exclusive choice of law in electronic contracts, see Dale Clapperton and Stephen Corones, 'Unfair terms in 'clickwrap' and other electronic contracts', 35 *Australian Business Law Review* (2007), 152.

[65] SI 1999/2083.

commerce through its third-party applications.[66] Schedule 2 provides a non-exhaustive list of terms which may be regarded as unfair; among these at paragraph 1(q) is 'excluding or hindering the consumer's right to take legal action or exercise any other legal remedy'.

The Rome I Regulation[67] came into force across the EU at the end of 2009. If a case is raised in the UK or another member state of the European Union, Rome I applies. Again, there may be a question over whether the user's agreement with Facebook can in fact be regarded as a 'consumer contract' within the scope of the Regulation,[68] but the future of e-commerce makes this matter critical. Article 3 provides that the parties may choose the law applying to the contract. Article 8 provides that the existence and validity of the contract or any term of it is to be decided by the law which would govern it if it were valid. However, under Article 3(2),'[t]he fact that the parties have chosen a foreign law, whether or not accompanied by the choice of a foreign tribunal, shall not, where all the other elements relevant to the situation at the time of the choice are connected with one country only, prejudice the application of rules of the law at the country which cannot be derogated from by contract'. It could however be difficult for a typical Facebook user to show that all the other elements relevant were 'connected with one country only.'

It is also unclear as to whether the Facebook 'agreement' overrides protection given in other jurisdictions, even to the extent of also overriding constitutional protections.[69] Similarly, is it also applicable to those who are below the age at which they can give irrevocable consent? This question is pertinent because Facebook explicitly permits persons of 13 or over to register as users. In the UK full capacity to contract is not attained till the age of 16 in Scotland and 18 in most of the rest of the UK,[70] and majority as regards contract is not attained

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[66] Also consider here the Consumer Protection (Distance Selling) Regulations 2000 and the Electronic Commerce (EC Directive) Regulations 2002.

[67] Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I). Thanks to Elizabeth Crawford and Janeen Carruthers for drawing our attention to this instrument.

[68] This is defined in Art. 5(1) as 'a contract the object of which is the supply of goods or services to a person ('the consumer') for a purpose which can be regarded as being outside his trade or profession, or a contract for the provision of credit for that object'.

[69] Given that most constitutional protections exist vis-a-vis the state rather than private corporations, in most circumstances these rights will be inapplicable anyway, but consider here, for example, the protection of the visual image under German intellectual property law and the constitutional law governing the dignity of the person.

[70] See the Age of Legal Capacity Act 1991, s. 1, in Scotland; and the Family Law Reform Act 1969, s. 1, in England. Below that age, the position is governed by common law and incidentally the Minors Contract Act 1987; minors can only contract in limited circumstances. These include contracting for 'necessaries' (*Nash* v *Inman* [1908] 2 KB

before 18 in California, thus making it unclear how minors can make a binding assignation licensing their intellectual property rights (some in perpetuity) to Facebook and its developers in this way, even setting aside the conflict of laws question. As yet there is no definitive answer to any of these questions of jurisdiction; there has been speculation that Facebook's broad licence is an underhand way of bypassing EU and UK legislation, but there is no clear evidence of this. What is obvious, however, is that Facebook adds to the already lengthy jurisdictional challenges posed by cyberspace.

3.7. Limiting the Licence?

As has been illustrated so far, many of the concerns raised and legal questions posed by Facebook stem from the breadth of the licence agreed to by users at the point they join the social network. In this section we question whether such an expansive licence is, in fact, required and consider this in terms of both the lasting effects and scope of the licence.

3.7.1. 'You can check out any time you like...'

As if a 'non-exclusive, transferable, sub-licensable, royalty-free, worldwide licence' was not enough, Facebook's Statement also announces that deleted content will be kept in back-up copies for a reasonable period of time.[71] This means, essentially, that even if a user chooses to leave Facebook, there is no guarantee that their information will be deleted; on the contrary, this implies that it will be deliberately kept, with 'reasonable' left undefined. Even with this considered, leaving Facebook was until recently much easier said than done. Before February 2008, if a user did opt for the drastic solution of trying to reassert full control over their property and ending the licence, they found that they had simply 'deactivated' the account, which, in fact, deletes nothing: all the information is archived in case the user decides to reactivate the account in future. A user who wanted all their data to be destroyed had to delete it themselves, every last bit of it, item by item. This can be no easy task for a previously active user, who may have thousands of items on their own and others' pages, and even then there was no guarantee that all contact details had finally been removed. For example, a Facebook user called Nipon Das went through this painstaking process and removed all the data on his profile, but

1), which is a concept broader than the ordinary meaning of the words would imply. See also the Age of Majority Act 1969 (Northern Ireland) as regards reaching full age in Northern Ireland.

[71] Statement of Rights and Responsibilities, *supra* note 15.

then reported that a journalist was nevertheless able to contact him through his empty profile.[72] The UK Information Commissioner negotiated with Facebook following a complaint about a similar case in which a British user had to contact the press before Facebook finally deleted his account.[73] Somewhat ironically one user, Steven Mansour, set up a Facebook group on 'How to leave Facebook'.[74] The company has now simplified the process,[75] but information on the procedure is only accessible through its help pages and the default - which is all that appears to be on offer, unless one searches for the alternative - is 'deactivating'. Many will not realise that this leaves all their data where it was - indefinitely. Facebook states that the data will then be inaccessible to other Facebook users[76] but as we have seen, other individual users are only one hole in the leaky tub. Meanwhile, all the data posted by other users – such as photographs, for example – of course remains in place.[77]

Why make it so difficult for users to leave and to delete their information? It is reasonable to build in some delay for the protection of the user against ill-considered deletion of an account, or malicious deletion by others. This does not however justify the extent of the barriers Facebook had erected and have only reluctantly begun to remove. Rather, Facebook can make the case that they need comprehensive licences and exemptions – even at the point at which the contract otherwise ends – because the commercial value of the sites rests in their number of users. If the owners of Facebook wish to sell, the site is worth little unless all the users and all of their personal data can be transferred to the buyer without the need to obtain the individual consent of millions of users. No doubt it also helps if inactive 'deactivated' accounts can remain part of the user tally, thus

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[72] http://www.iht.com/articles/2008/02/11/business/11facebook.php (accessed 26 February 2010).

[73] House of Lords Select Committee on the Constitution, 2nd Report of Session 2008–09, *Surveillance: Citizens and the State* Volume I: Report, London: Stationery Office 2009, para. 42.

[74] http://www.stevenmansour.com (accessed 26 February 2010); see also the link to the group: 'How to permanently delete your facebook account', run by Magnus Wallin.

[75] https://ssl.facebook.com/help/contact.php?show_form=delete_account (accessed 26 February 2010).

[76] http://www.facebook.com/help/?page=842 (accessed 26 February 2010).

[77] Facebook were not alone in placing obstacles in the path of those who wish to leave: MySpace and Friendster were notorious for their practice of requiring users to confirm repeatedly that they want to leave permanently before they were offered an opportunity to delete the account. It is more straightforward to close a Bebo account, although we experimented with this and found that it took several days for the profile to become inaccessible through a search.

inflating the value of the enterprise.[78] Certainly, a broad licence is a potentially immense asset, but it is arguable that Facebook would be able to provide a similar service without it; it is the fact that it chooses not to that, more than anything, marks Facebook out as a fundamentally commercial enterprise.

3.7.2. Possible Alternatives

We argue that Facebook would be able to provide the service it does without such a broad licence, without such broad sharing of data with marketers, and without lengthy retention of sensitive personal data after a person has requested that their account and all record of it be deleted. The issues raised here are both technical and commercial.

From a technical perspective, it should certainly be possible for all data uploaded by an individual to be tagged with a unique identifier so that there could be saturation deletion of all a user's content (live and archive copy) when they delete the account, with the exception of material that was never theirs, such as any photos uploaded by another user. Even here however, if the picture has been tagged with the first user's Facebook ID, it should not be difficult to monitor this and include it in a total deletion.[79] Users could also be given the facility to 'lock' data so that it cannot be electronically copied by other users (one only need think of Acrobat Reader, where information can be read but not edited).[80] It would, of course, be difficult to prevent copying through print-screen options, but this would nevertheless make it more difficult for users to cut, paste and print another user's personal information as they choose. Furthermore, although Facebook may argue that it needs the broad licence for commercial purposes, in order to maximise the value of the site, this fails to justify the relative lack of partial opt-outs. Under an opt-out system, users could offer a broad licence to sell, but not to use, all of their personal data or just some – again, this would return a great deal of control to the user.

As we have seen, then, several avenues of legal complaint could be pursued, and Facebook could be persuaded to offer better, more

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[78] Personal data changes ownership by means of company activities such as merger-acquisitions and reorganisations. See S. Gauthronet, "The Future of Personal Data in the Framework of Company Reorganisations", conference publication, 23rd International Conference of Data Protection Commissioners, Paris - September 2001.

[79] Such as the 'random number system' proposed by Phorm – in that case it is designed to facilitate anonymity, but it could arguably be utilised in the opposite way. For more on Phorm see section 8 below or www.phorm.com.

[80] For more on technological means of upholding property rights, see, for example, the discussion of 'technologies of identity' in P.E. Agre's article 'Beyond The Mirror World: Privacy & the Representational Practices of Computing', in P.E. Agre & M. Rotenberg (eds) *Technology & Privacy: The New Landscape* (MIT Press: Cambridge 2007).

flexible privacy opt-outs. Perhaps, though, offering such options provides a fanciful protection rather than a real one. At the very simplest, the privacy option would have to be the default, but this would not reflect the variety of privacy choices different users would wish to make. Chris Peterson has argued instead that the solution lies in a more intuitive privacy architecture in which the way users' information is dispersed resembles the way in which they would protect their privacy among real-life, visible audiences.[81] In a prescient study published in 2005, Alessandro Acquisti and Ralph Gross[82] found that student Facebook users at their own university, Carnegie Mellon, permitted an astonishing amount of sensitive personal data to be made public. Whether this was due to Facebook's misleading references to its 'core principle' of privacy, simply because of a lack of awareness, or because they did not much care,[83] students at the university actually used very few of the privacy options that Facebook already provides. The authors, simply by dint of being in that university 'network' on Facebook, were able to download 4540 profiles of the network's users, the vast majority of whom had concealed none of their data from the network. The findings of this study suggest that, even were Facebook to offer greater service provider-to-user or third-party-to-user protection, it is unlikely that such opt-out would be widely used.

3.8. Online Social Networking in the Future

It has been our intention in this paper to draw attention to some of the issues associated with online social networking and, particularly, the Facebook platform. Two main issues have been identified as regards the provider-to-user relationship, namely the 'privacy policy' issues of individuals' personal information in terms of the broad licence, and those relating to advertising targeted at potential consumers on the strength of information gleaned from uploaded personal information. While the fundamental concern of each of these issues is one of privacy, it would appear, however, that both the social attitudes towards and the legal treatment of these issues is very different, much

[81] 'Saving Face: The Privacy Architecture of Facebook', 2009, http://works.bepress.com/ cpeterson/1/ (accessed 26 February 2010).

[82] A. Acquisti and R. Gross, *Imagined Communities: Awareness, Information Sharing, and Privacy on the Facebook*, 2006, http://www.heinz.cmu.edu/~acquisti/papers/acquisti-gross-facebook-privacy-PET-final.pdf (accessed 26 February 2010).

[83] Acquisti and Gross, ibid., speculate that people tend to give truthful answers on Facebook because they are interacting with their friends, namely people who already know their name, birth date, sexual preferences and so on. This is very different from other, open-access sites such as MySpace, where there is much more incentive to create a fictional self or multiple identities.

of which could be said to stem from the position Facebook has in the wider context of online and technological advances.

Targeted advertising, for example, is not something that is specific to Facebook alone – on the contrary, Facebook is merely one locus out of many, and not even the largest one at that – the corollary of which is that they are simply part of the wider continuum of commercial digital data capture and use. This 'continuum' is becoming increasingly subject to regulation: the recently announced Internet Advertising Bureau UK (IABUK) Good Practice Principles of online behavioural advertising (OBA) can be cited as an example of industry self-regulation,[84] while another interesting development is the arrival on the scene of companies such as NebuAd in the US and Phorm in the UK, who are respectively promoting an alternative to what they term the recognised 'orthodoxy' of 'store and retrieve'.

On the other hand, the privacy policy issues are far less well-developed in terms of, specifically, their *legal* character, not least to the extent that it is actually still unclear whether or not this is an area that should be covered by legal provisions as such. For example, should the law *force* Facebook and other OSN sites to improve upon or even simply clarify their privacy policies, and – if so – how could this be effected? Would a mere display of a clear notice on the behalf of the provider be sufficient in providing the users with this information? Also, and perhaps most controversially, do the users actually *care* about this to any real extent? While the users and the Bloggers are 'rallying in support of copyright' in order to protect their work, as was discussed above, can it really be said that there is the same attachment to one's personal data? Is its 'gathering' and storage perceived as being a simple consequence of participation in OSN communities, a price that users are willing to pay for the privilege?[85] If there were to exist

[84] The drafting of these principles has been undertaken in collaboration with the American Association of Advertising Agencies (AAAA) and the Direct Marketing Association (DMA), along with many of the bigger players in the industry, although this list does not, it should be noted, include Facebook. These Good Practice Principles, which are due to come into force in the UK on 4 September 2009 are intended to be used by 'businesses that collect and use data for behavioural advertising' and are '[t]hey are based upon offering users notice about data collection, choice as to whether to participate and education about behavioural advertising and its benefits.' For further details see http://www.iabuk.net/en/1/behaviouraladvertisinggoodpractice.html (accessed 26 February 2010).

[85] One possible 'sweetener' could be that the individual gleans some benefit from inputting their personal data and related online practices, over and above that of simple utilisation of the platform; as Corien Prins states: 'Individuals make deals for the disclosure, collection, use and re-use of their personal data [and] in certain situations receive some form of compensation [...] and thus 'exploit' and 'sell' their habits, user-profile and individual data'. See C. Prins, *supra* note 27 at 275.

some form of legal recourse for a complaint of this nature, would such a complaint be forthcoming?

With online social networking still being in its comparative infancy, it is impossible to provide answers to these and similar questions with any degree of certainty, although we would tentatively suggest that much of the development of the law in this area will depend upon which of the many differing social attitudes towards online privacy ends up eventually prevailing. With these different attitudes being spread across various sectors of society (most notably age-group),[86] however, it is far from clear whether it is possible that a genuine consensus be achieved. Indeed, in terms of access and control of personal information posted online, it appears that an exploration into what is in fact considered to be *private* is required before the law can make much of an attempt to regulate OSN providers such as Facebook.

[86] 'In the past ten years a new set of values has sneaked in (...), erecting another barrier between young and old. (...) [T]he older generation has responded with a disgusted, dismissive squawk: Kids today. They have no sense of shame. They have no sense of privacy. They are show-offs, fame whores, pornographic little loons who post their diaries, their phone numbers, their stupid poetry – for God's sake, their dirty photos! – online.' And the opposite perspective: 'More young people are putting more personal information out in public than any older person ever would – and yet they seem mysteriously healthy and normal, save for an entirely different definition of privacy. From their perspective, it's the extreme caution of the earlier generation that's the narcissistic thing.' See Emily Nussbaum's *New Yorker Magazine* article, 12 February 2007: http://nymag.com/news/features/27341/ and Vicky Allan's related article in *Sunday Herald*, April 4, 2009: http://www.sundayherald.com /search/display.var.2499891.0. meet_the_bebo_generation.php (accessed 26 February 2010).

Chapter 4. How Can Hybrid Nanomedical Products Regulation Cope with Wicked Governability Problems?

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Abstract
Nanomedicine is an area of nanotechnology that raises high expectations due to to its potential in diagnostics, drug development and delivery, and other health-related applications. This paper discusses the lessons for the regulation of nanomedical products that the European Union's medical product regulation can teach. Specific attention is paid to the Advanced Therapy Medicinal Products Regulation. The paper assumes that nanomedical product regulation requires a sophisticated hybrid regulation approach. The evaluation of the European medicinal products regulation leads to four specific lessons for nanomedical product governance. Another, more general lesson is that the centralisation of product safety, quality and efficacy knowledge and the coordination of vigilance information are essential to cope with the uncertainty, complexity and ambiguity of risk problems associated with nanoproducts.

4.1. Introduction

Nanotechnological development poses new challenges to regulatory risk governance. It seems to add a new dimension to the uncertainty, complexity and ambiguity of risk problems that technology regulation usually has to cope with. This is the unpredictability of technological development (Dupuy, 2007; Randles, 2008). Due to the knowledge gaps related to nanotechnological risks, specific legislation cannot yet be created. This does not mean, however, that public policy can wait and see. Even in the case of deficient evidence, public responsibility goes beyond a *laissez-faire* approach to risk regulation (European Commission (EC), 2004; EC, 2006). It requires precautionary regulatory action when basic values like human dignity, health, safety, environment, property, and privacy are at risk (EC 2000; Fisher 2007). In the current debates on regulating nanotechnologies, scholars and policy makers seem to agree that combining various regulatory methods is the most appropriate approach to cope with the governability problems of nanotechnological development (EC 2004; Bowman and Hodge 2007; Marchant et al. 2008). A basic expectation is that public regulation can benefit from joint policy- and rule-making

activities to come to grips with the nanotechnological governability problems.

This paper explores how nanomedical regulation can cope with its governability problems.[1] It assumes that nanomedical product regulation requires a sophisticated hybrid regulation approach. Nanomedicine is an area of nanotechnology that raises high expectations with regard to its potential in diagnostics, drug development and delivery, and other health-related applications. This paper discusses the lessons for the regulation of nanomedicinal products that the European Union's (EU) medical products regulation can teach. Specific attention will be paid to the Advanced Therapy Medicinal Products (ATMP) Regulation (1394/2007/EC), which merges gene, cell, and tissue engineering therapies into one regulation. This is a particularly interesting example of hybrid regulation, which aspires to satisfy a wide range of stakeholder interests as well as to integrate some components of the EU's medical devices regulation into its drugs regulatory mode. This paper explores what can be learned from the ATMP Regulation to cope with effectiveness and legitimacy problems of nanomedical regulation. To set the stage I will start with an overview of the specific governability problems of nanomedical products. Then I will discuss responses to these regulatory challenges. I will focus on prudent regulatory hybridisation. In the current public governance debate, hybridisation of governance modes, methods and instruments is regarded as a particularly promising regulatory approach (Trubek and Trubek, 2005; Trubek et al., 2006; Halpern, 2008). In the next step, the prudent potential of the ATMP Regulation will be analysed in the context of the EU's medical products regulation system. Finally, I will deal with the lessons that can be learned from this case.

4.2. Specific Governability Problems of Nanomedical Products

4.2.1. Regulatory Gaps Related to Nanomedical Products

Nanomedicine is defined as "the science and technology of diagnosing, treating and preventing disease and traumatic injury, of relieving pain, and of preserving and improving human health, using molecular tools and molecular knowledge of the human body" (European Science Foundation, 2005). Currently, research efforts are particularly intensive with regard to new methods and tools for diagnostics (e.g., 'lab-on-a-chip' devices, biosensors), screening and imaging (e.g., smaller, more efficient and cheaper cameras for whole body imaging), as well as to

[1] Following Van Kersbergen & Van Waarden (2004, 156), we understand by governability "the capacity to solve urgent societal problems" or "to realise policies".

drug development (nano-pharmaceuticals) and delivery (e.g., 'targeted nanocarriers'), and gene therapy (Dutch Health Council, 2006; European Group on Ethics in Science and New Technologies (EGE), 2007). Furthermore, research is underway into applications in fields such as disinfection (nanoparticles of silver), tissue engineering (e.g., nanostructure scaffolds for tissue replacement) and medical implants. Although nanomedicine is in its infancy, it is advancing rapidly. A few products are already on the market, other products are almost ready for clinical use. For instance, diagnostic techniques for the rapid detection of leukaemia based on nanotechnologies and nano-pharmaceuticals are already available (EGE, 2007: 17). According to a Working Group of the European Medicines Agency (EMeA), the majority of current commercial applications of nanotechnology to medicines is geared towards drug delivery to enable new modes of action, as well as better targeting and bioavailability of existing medicinal substances (EMeA, 2007).

As nanomedical structures are multifunctional, the lines between medicinal products, medical devices and biologic products may become increasingly blurred and new modes of action may be created. Since nanomedical applications are characterised by combinations of modes of action on the human body ('hybrid' or 'borderline' products[2]), they may fall either in none or in one or more regimes of the EU's medical products regulation system (drugs, medical devices and biologic products regulation). When two or three medical regulation regimes are applicable, questions arise whether one of these regimes is a *lex specialis* and whether hybrid nanomedical products need a new regulatory regime. When future nanomedical applications create new modes of action or modify the existing ones, the current EU medical products regulation system may not be sufficient. For instance, diagnostic systems based on nanotechnologies may require the adaptation of EU medical devices regulation, but this novelty may also call for a new regulatory regime. Hence, governability problems are raised by uncertainties about regulatory gaps. They are also induced by specific problems of effective and legitimate nanomedical regulation.

[2] See, for borderline issues in relation to human tissue-engineered products, Kent et al. 2006, p. 45.

4.2.2. Problems of Effective and Legitimate Nanomedical Product Regulation[3]

Regulatory effectiveness depends on the degree to which determined policy objectives are achieved by the use of certain regulatory instruments (Opschoor and Turner, 1994: 11). Basic objectives of public technology regulation are risk management, the facilitation of commercial transactions, and the generation of public trust in technological products (Van Waarden, 1996; Franzius, 2001; Vogel, 2001; Kent et al., 2006; Newell, 2002; Dorbeck-Jung, 2007). More specifically, public nanomedical product regulation aims at providing for the safety, quality, and efficacy of these products, as well as at facilitating beneficial medical technology product innovation. Generally, effectiveness problems refer to regulatory implementation and compliance deficiencies, as well as to other unexpected effects that inhibit policy goal achievement. In product regulation, specific effectiveness problems arise when consumers reject beneficial products because they do not trust regulatory controls.

Trying to meet the objectives of technology regulation, public regulators encounter difficulties to cope with conflicts of stakeholder interests, as well as with contradictory requirements of effective and legitimate regulation. Conflicts between recognised interests are the consequence of potential contradictory jobs of public regulation. For instance, interest conflicts may arise where the promotion of technology is inhibited by certain protective measures of regulatory risk management, or, vice versa, where regulatory facilitation of product development puts health, safety, and privacy rights at risk. Patients and industries have an interest in the quick marketing of safe and effective nanomedical products: patients for improving their health, and industry for the sake of profit-making (including credibility profits). As safety and efficacy management may take a considerable amount of time, and as it is accompanied by high research and development costs, safety and efficacy interests may potentially conflict with promotion concerns. For small and middle-sized enterprises, research and development costs represent a significantly larger proportion of their spending than they do for the big players. Public regulators are required to strike a balance between stakeholders' interests.

Legitimacy problems arise when public regulators do not follow the principles of good governance and when the goals of these principles are not achieved. By legitimacy we refer to the acceptability of regulation (Dorbeck-Jung, 2008). In the EU the legitimacy of regulation

[3] The normative requirements of public regulation also include efficiency. In this paper, the focus lies on effectiveness and legitimacy requirements.

is about meeting the principles of openness, democratic decision-making and participation, accountability, proportionality, subsidiarity and coherence of regulation.[4] In nanomedical product regulation, legitimacy problems may arise when unelected experts contribute to regulatory decision-making.

Regarding the knowledge gaps related to coming nanomedical applications, complex risk problems, potential regulatory gaps and potential effectiveness and legitimacy problems, we speak of 'wicked' governability problems that are highly resistant to regulatory solutions.[5]

4.3. Responses to Governability Problems: Prudent Hybridisation

4.3.1. Expected Advantages of Hybrid Regulation

In our introduction we assumed that governability problems induced by nanomedical products may be reduced by regulatory hybridisation. By hybridisation we understand more or less loosely coupled combinations of governance modes, methods and tools.[6] Regulatory gaps may be bridged by combining or integrating regulatory modes,

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[4] These requirements are mentioned in the White Paper on European Governance (EC, 2001). See also the discussion of good governance principles in relation to pharmaceutical governance in Dorbeck-Jung and Oude Vrielink, 2007.

[5] The terminology of wicked problems was originally proposed in 1973 by H.W.J. Rittel and M.M. Webber, both urban planners at the University of California, Berkeley, USA. In a landmark article, the authors observed that there is a whole realm of social planning problems that cannot be successfully treated with traditional linear, analytical approaches. They called these issues 'wicked' problems and contrasted them with 'tame' problems. Currently, the terminology is applied to policy problems that are difficult to clearly define, socially complex and multi-causal, that have unforeseeable consequences and cannot be solved (Australian Public Service Commission, retrieved from http://www.apsc.gov.au/publications 07/wickedproblems2.htm,
(accessed 26 February 2010).

[6] In a more ambitious approach, hybridisation is understood as an integration of different modes, methods and tools that generates new governance forms (Brandsen et al. 2006). In view of the aim of this paper, a more modest approach seems appropriate. With regard to *governance modes* we focus on combinations of hierarchic and non-hierarchic regulation. These combinations are located on a continuum, starting with hierarchic modes and ending up with non-hierarchic governance modes. In relation to *governance methods* we concentrate on co-regulation. In public governance, co-regulation is about dispersing public regulatory authority within joint regulatory activities (Börzel and Risse 2005). Forms of co-regulation are joining public and private controls, engaging a multiplicity of actors in public regulation, and combining levels of regulation, for example, central and local. With regard to *governance tools* we focus on combinations within law, that is to say hard and soft law. Hard law refers to rules of conduct which have legally binding force, i.e., legislation. By soft law we understand rules of conduct which in principle have no legally binding force, but which nevertheless have effects in legal practice (Synder 1995). Examples of soft law are public and private action plans related to nanotechnology, codes of conduct, best practices and standards.

methods and instruments of the various EU medical products regulation regimes. Regulatory hybridisation seems to be an appropriate approach to respond to the regulatory needs of hybrid nanomedical products. Hybrid governance modes, methods and instruments seem to be better equipped to cope with the unpredictability, uncertainty, complexity and ambiguity of nanotechnological development and its risk problems than 'pure' governance forms (Van Calster, 2006; Dorbeck-Jung and Van Amerom, 2008; Kearns and Rip, 2008). Co-regulation and soft law allow for reflective learning processes, experimentation and adjustment of regulation in response to new insights into nanotechnological risks. Initiatives of public engagement and stakeholder dialogue are said to support the acceptance of nanoproducts.

In the new public governance literature, governance hybridisation is regarded as a means to enhance the effectiveness, efficiency and legitimacy of regulation (Teubner, 1997; Gunningham et al., 1998; Pierre and Peters, 2000; Mayntz, 2002; Trubek and Trubek, 2005; De Búrca and Scott, 2006; Trubek et al., 2006; Heritier and Lehmkuhl, 2008; Halpern, 2008). It is an attempt to improve regulation by means of satisfying a large number of involved interests in order to increase decision-making capacity (Hey et al., 2007). Regulatory hybridisation is intended to create win-win situations in which public and private interests are attained (Gunningham et al., 1998). It is expected to create mutual trust and understanding and to enhance regulatory quality, including compliance rates and the social legitimation of regulation (Garcia Martinez et al., 2007). Alliances of hard and soft law are used to combine the advantages of both instruments. This is to say that these instruments are connected to provide for openness, flexibility, simplicity and low negotiation costs ('soft law's beneficial capacities'), but also for binding force, predictability, stability, due process, accountability, and transparency ('hard law's beneficial capacities'). According to empirical studies, the hybridisation of regulatory instruments can be more advantageous than the use of only one particular 'pure' type of regulation if certain conditions are met (Halpern, 2008). This seems to be the case when regulators have to cope with 'wicked' governability problems (Dorbeck et al., 2009).

4.3.2. Prudent Hybridisation

In order to tackle the 'wicked' governability problems we mentioned above, public regulators have to make competent normative decisions in concrete regulatory situations. This is the aspiration of prudent regulation (Selznick, 1992; Dupuy & Grinbaum, 2004; Dupuy, 2007; Dorbeck-Jung, 2007). Prudent hybridisation of nanotechnological

regulation takes into account general insights of how to achieve legitimate and effective technology regulation. It also draws on specific experiences with hybrid regulation. In this section we deal with the general and specific requirements of prudent regulation.

With regard to legitimacy principles, we referred above to the European criteria of good governance (EC 2001): openness, democratic decision-making and participation, accountability, proportionality, subsidiarity and coherence of regulation. *Openness* includes the transparency of regulation, learning from successes and failures of other regulation, flexibility and ongoing review of regulation. Traditionally, *democratic decision-making* refers to public regulation based on decisions of parliament. Democratic decision-making is closely related to the principle of legality ('public action that affects constitutional rights must be based on law, and public regulators regulate under the conditions of law'). When public regulation is combined with private regulation for the sake of enhancing effectiveness, regulatory hybridisation is taking place in the 'shadow' of public authority. Public regulators are required to establish a legal frame related to the whole nanoproduct cycle (including pre-marketing, approval, manufacturing, marketing and post-marketing controls[7]) in order to safeguard constitutionally recognised rights. In case of low regulatory performance of non-governmental regulators, more specific legislation, public enforcement actions and law suits may be needed. In joint public-private regulatory activities, comprehensive participation of stakeholders (including patients, doctors, manufacturers, and member states) is required to compensate for the lack of democratic decision-making. Participation of stakeholders is also important to enhance the acceptance of nanomedical products. *Accountability* is closely related to the ideals of openness. Both principles require the transparency of decision-making. Accountability calls for clear formulation and adequate distribution of the actors' responsibilities. To prevent regulatory capture ('biased interest recognition') impartiality and independence of decision-makers are required. Where public and private stakeholders closely collaborate in regulation, special attention should be paid to accountability controls. *Proportionality* refers to the accommodation of interests. More specifically, this principle means that nanomedical regulatory action must be in proportion to risk problems. Furthermore, it requires unbiased balancing of (conflicting) protection and technology promotion interests. In EU governance

[7] The terminology of 'regulatory product cycle' refers to regulatory controls regarding the stages of pre-marketing, approval, manufacturing, marketing, and post-marketing of medical products (see Kaufer 1990).

policy, *subsidiarity* refers to the regulatory sovereignty of the member states. This principle is particularly important in regulatory fields like health care, where the member states still have more regulatory competencies than the Community.[8] Where EU regulation does not permit member states to follow their own political morality (for example, to set higher or lower safety standards), national sovereignty may be affected. *Coherence* involves the continuity of regulatory systems. Legitimacy problems may arise when new nanomedical regulation does not fit within the approaches used in the EU medical products regulation system. Regulatory coherence is fostered by the stability of a regulation system.

The *effectiveness* of nanomedical product regulation may be enhanced by grounding regulatory design in empirical knowledge of compliance successes in other examples of technology regulation. To improve its effectiveness, legislation should leave room for private regulation, soft law, and regulations at other government levels. Legislation should provide for flexibility, experimentation and continuous review according to increasing knowledge about nanotechnological risks and regulatory effects. To cope with the uncertainties of nanomedical applications and their impact, *vigilance* provisions are regarded as an important regulatory measure (Lösch et al., 2008; Randles, 2008). Accordingly, continual monitoring of nanomedical development and collaboration with technology assessment studies seem to be essential for prudent technology regulation. When new insights into risk problems and technical progress become available, existing regulation must be open to review and modification.

To sum up, basic questions for assessing effective and legitimate (prudent) hybridisation of nano(medical) regulation are:

1. Does public regulation provide for a general public regulation/legal frame for the whole nanomedical product cycle?
2. Does the (legal) frame provide for ongoing review of regulation?
3. Are there any legal provisions that stimulate experimentation with hybrid regulation?
4. Does the (legal) frame leave room/enough flexibility for (semi-) autonomous private regulation, soft law and regulatory activities with other stakeholders?

[8] In this sector, the EU regulatory competencies are rather limited. According to Article 168 of the Lisbon Treaty, the EU is empowered to protect human health, and more specifically to provide for the quality and safety of human organs, material and blood. Other relevant regulatory competences refer to consumer protection (Article 169) and free movement of products across the EU (Article 28).

5. Does the legal frame provide sanctions for low regulatory performance of non-governmental regulators?
6. Does the regulatory regime provide for continual vigilance?
7. Is the regulatory regime based on empirical insights into the effectiveness of governance hybridisation and earlier technological risk regulation?
8. Do stakeholders participate in decision-making concerning the legal frame?
9. Are promotion and protection interests comprehensively and unbiasedly balanced?
10. Is public acceptance of regulation fostered and if so, by which regulatory means?
11. Is transparency of regulation provided for?
12. Is accountability of regulators provided for?
13. Does EU regulation leave room for the political morality of the member states?
14. Is the regulation coherent with its regulatory system?

In the next section we will explore the prudent potential of the EU Advanced Therapies Medicinal Products Regulation in the context of the EU medical products regulation system. We start with a brief history and the scope of the ATMP Regulation. Then, specific attention will be paid to hybrid components of this regulation.

4.4. Prudent Potential of the EU Advanced Therapies Medicinal Products Regulation[9]

4.4.1. Brief History and Scope

The ATMP regulation is part of the EU medical products regulation system, which includes the regulatory regimes of medicinal products, medical devices and biologic products. The EU pharmaceuticals regulation was established in the 1960s, while the European medical devices regulation was laid down thirty years later. EU biologics legislation emerged ten years later than the medical devices legislation. In 2001, specific regulation of blood and blood products was established (2001/83/EC). In 2004, Directive 2004/23/EC set standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells. These activities were followed by Regulation 1394/2007/EC on advanced therapies medicinal products.

[9] This case study is based on policy and legislative documents, the relevant literature and the empirical studies of Kent et al. 2006.

The EU ATMP Regulation is a *lex specialis* which introduces additional provisions to those laid down in Directive 2001/83/EC on medicinal products. This means that the general provisions of the EU pharmaceuticals legislation apply to ATMPs,[10] as far as there is no specific regulation. Regulation 1394/2007/EC supplements Directive 2004/23/EC on medicinal products with additional standards of quality and safety, where appropriate. Combined advanced therapy medicinal products ('borderline products') are always regulated under the ATMP regime.

4.4.2. Hybrid Regulation?

The ATMP Regulation follows the regulatory approach of the EU's pharmaceuticals regulation. In all stages of the regulatory product cycle (pre-marketing, approval/rejection/withdrawal, manufacturing, marketing, post-marketing), ATMPs are primarily governed by mandatory legislation, which is accompanied by soft law including standardisation, codes of conduct and principles of good practices. ATMP regulation, however, also entails some components of the medical devices approach, including the certification of quality. In the *pre-marketing stage*, Regulation 1394/2007/EC allows small and medium-sized enterprises developing an ATMP to apply to the EMeA for scientific evaluation and certification of studies necessary to demonstrate the quality and non-clinical safety of ATMPs (Article 8).

The *approval* of ATMPs is governed by the centralised procedure of drugs authorisation. This mandatory procedure is based on standardisation of the ICH (International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, see Dorbeck-Jung, 2008), which is a joint activity of the pharmaceutical industry and the drugs agencies. What is new is the establishment of the EMeA's Committee for Advanced Therapies. This Committee of high level experts is consulted in the authorisation process. Hybrid products are controlled by hybrid regulation. ATMPs that incorporate medical devices or active implantable medical devices must meet the essential requirements laid down in the Medical Devices Directives (Articles 6-9, Regulation 1394/2007/EC).

Post-marketing regulation focuses on the information system on suspected adverse effects and events of drugs (*pharmacovigilance*).

[10] According to article 1 Regulation 1394/2007/EC, an advanced therapy medicinal product covers a gene therapy medicinal product, a somatic cell therapy medicinal product, as well as a tissue-engineered product. Particular ATMPs prepared on a non-routine basis and used in a hospital for an individual patient are excluded from the scope of this Regulation.

Pharmacovigilance information is based on standards that have been set up in the Community. Further standardisation is sought in collaboration with the World Health Organisation. The information system is a collaborative activity of the EU and its member states. It is coordinated by the EMeA. Additionally, the ATMP Regulation has laid down specific provisions regarding post-authorisation risk management and the follow-up of efficacy and adverse reactions (Article 14). These provisions include additional reports and evaluations. Furthermore, the traceability of advanced therapies medicinal products is regulated within post-marketing controls.

We can conclude that the ATMP regulation (including general pharmaceutical regulation) provides for regulatory hybridisation in terms of using various modes, methods and instruments. Although there are some less hierarchical elements in the ATMP regulation, the whole regime seems to be hierarchical rather than non-hierarchical. This is also the case with borderline products with ATMP and medical devices modes of action. For these products the ATMP regulation integrates less hierarchic components of the medical devices notification procedure within the hierarchic centralised pharmaceuticals authorisation procedure. Co-regulation is taking place with regard to standard-setting activities in the pre-marketing and approval stages of the regulatory product cycle. In the stages of manufacturing and marketing, joint regulatory activities of manufacturers, ATMP industry, patients and the EMeA are provided. Post-marketing surveillance and the enforcement of the ATMP regulation are entirely based on public regulation. In addition to the tight legal controls a wide range of soft law has emerged in the general pharmaceutical regime. Obviously, the EU has taken a regulatory stance of sophisticated hybridisation, which integrates advantageous components of private regulation and soft law into a dominant hierarchic central approach.

In the next section we explore the prudent potential of the ATMP regulations, trying to answer the 14 questions we formulated above.

4.4.3. Questions 1 to 5 on the Legal Frame

1. Legal frame.

The general EU drugs regulation and the specific ATMP Regulation provide a legal frame for the whole product cycle. Standards on clinical trials and on approval requirements that have been set up by the ICH have been codified in EU regulation.

2. Ongoing regulatory reforms.
In the pharmaceutical regime the legal frame has stimulated ongoing regulatory review and regulatory reforms. During the forty years of EU medicinal products regulation, a number of major reforms have taken place. According to the ATMP Regulation, the European Commission is obliged to publish a general report on the application of the Regulation by 30 December 2012. In this report special attention must be paid to the impact of technical progress. Regulatory reforms are also required in relation to the adaptation of the Regulation's Annexes according to scientific and technical evolution.

3. Experimentation with hybrid regulation.
This is not regulated.

4. Room for private regulation and flexibility.
The legal frame does not leave much room for self-regulation of manufacturers, ATMP industry and other stakeholders. It is striking that this room was broader in the past. It has been reduced in the last reforms of the general pharmaceuticals regime by legislative specification of the legal requirements for private codes of conducts, risk assessment and quality management systems. Although the ATMP Regulation emphasises the need of regulatory procedures that provide for sufficient flexibility,[11] so as to easily accommodate the rapid evolution of science and technology, the overall flexibility of the regulatory regime does not seem to be high.

5. Sanctions.
According to the general EU pharmaceuticals regulations, member states are obliged to provide for sanctions for low regulatory performance of applicants, manufacturers, etc.

4.4.4. Question 6 on the Vigilance Regulations

6. Vigilance.
Surveillance of medicinal products is provided during the whole regulatory product cycle. In the pre-marketing stage, pharmacovigilance procedures are used to ensure the immediate cessation of any clinical trial where there is an unacceptable level of risk. Investigators and sponsors are legally obliged to monitor and to report all serious suspected adverse events and reactions. Post-marketing surveillance seems to be continual and comprehensive. In the 2004 regulatory reform of the pharmaceuticals regulation, pharmacovigilance was

[11] See Preamble (13) Regulation 1394/2007/EC.

enhanced according to new communication techniques. The collaboration with the World Health Organisation has been intensified. Effective vigilance is supported by a wide range of legal obligations related to information communication. Penalties are provided for non-compliance. According to a study on the transparency of the EU medicinal products regulatory system, however, doubts arise whether the vigilance information provided is up-to-date and understandable (Van Lessen Kloeke and Artz, 2006).

4.4.5. Questions 7 to 14 on the Quality of Regulation

7. Based on empirical insights.

The ATMP Regulation has not been based on an evaluation on the effectiveness of the existing EU medical products regulation system. The 2005 Consulting Paper of the European Commission refers only to a study by its Institute for Prospective Technological Studies on the markets and future prospects of human tissue-engineered products (EC 2005). The empirical investigations of Kent et al. (2006; funded by United Kingdom organisations) and Heinonen et al. (2005; funded by Finish organisations) have not been mentioned in the relevant EU policy papers.

8. Stakeholder participation.

According to influential accounts, the ATMP Regulation is a good example of the emerging 'participative ethos' within EU medical products regulation (Kent et al., 2006; Salter and Jones, 2002). This means that there is increasing attention for the role of the consumer-citizen within the regulatory process. While the participation of consumers in the 2004 EU Human Tissues and Cells Directive was marginal and limited to specific patient groups, consumer participation seems to have been broader and more substantial in the ATMP's regulatory process. In 2002 stakeholders were consulted via internet on the need for a community legal framework on 'human tissue engineered products'. After the last reforms of the EU drugs regulation, two representatives of a European patient organisation were included into the EMeA's Management Board.

9. Balancing of recognised interests.

In the evolution of the medicinal products regulatory regime, we observe a tendency of providing increasing incentives for quick marketing and product innovation. The ATMP Regulation has laid down specific incentives for (bio-)medical industry, such as minimum level fees and specific support for small and medium sized enterprises. On the other hand, safety, quality and efficacy requirements have been

specified in the last reforms of the drugs regulatory system and within the new ATMP Regulation. Without further empirical research it is not possible to conclude whether this increased attention for promotion concerns is proportional in relation to regulatory measures on ATMPs' safety and efficacy.

10. Support for public acceptance.
Public acceptance is supported by the emerging 'participative ethos' within EU medical products regulation. It is also fostered by increasing transparency of the EMeA's decision-making and the Agency's soft law, as well as by pharmacovigilance information about suspected adverse effects of drugs. Exceptions are made for the sake of commercial secrecy. The 2006 investigation of Van Lessen Kloeke and Artz indicates, however, that there may be problems with regard to effective transparency in terms of understandable and up-to-date information.

11-12. Transparency and accountability measures.
In the last reforms of the EU's pharmaceutical regulation, accountability provisions were enhanced. The new provisions refer to the specification of the tasks and obligations of the members of the EMeA's Management Board and Scientific Committee, as well as job rotation, interest declaration and the acceptance of gifts. Information about interests is accessible to the public. Regulation 726/2004 requires that the database on medicinal products is managed independently of pharmaceutical companies. In addition to the general drugs regulation, the ATMP Regulation requires members and alternates of the EMeA's Committee for Advanced Therapies to have no financial or other interests in the biotechnology sector or medical device sector that could affect their impartiality (Article 22).

13. Subsidiarity.
By focusing mainly on technical issues, the ATMP Regulation basically sidesteps different views of the member states on certain ethical issues with the 'subsidiarity' principle (Sanzenbacher et al., 2007).[12] This means that the ATMP Regulation will not interfere with national ethical decisions on accepting the use of specific cell types, such as human embryonic or fetal cells, primordial cell types or therapies derived from those cells. Member states seem to remain free to enact their own legislation that forbids the use of some cell types or therapies on their national territories.

[12] See also *http://www.europabio.org/events/IndustryHearing/index.htm* (accessed 26 February 2010).

14. Coherence.

The regulatory approach of the ATMP Regulation seems to fit nicely within the pharmaceutical regulation regime. With its focus on a centralised authorisation procedure, the Regulation provides for the continuity of the drugs regime. By integrating some components of the medical devices regime into the medicinal products approach in case of hybrid ATMP's which also have a mechanical mode of action, the Regulation enhances the coherence of the EU medical products regulatory system.

4.5. Conclusions: Lessons to be Learned

In this paper, we have explored the lessons for nanomedical product regulation that can be learned from the recently established EU ATMP regulations. The focus of our exploration lies on the successes and problems of regulatory hybridisation.

Lessons for nanomedicinal products to which the ATMP regime applies

1. Nanomedicinal products to which the ATMP regime (including the general drugs regulations) applies will be governed by a mainly compulsory regime which allows for little regulatory hybridisation and little flexibility. This does not stimulate experimentation with hybrid modes and methods of regulation, but it does provide for high safety and efficacy standards, as well as for a rather effective vigilance system and regulatory continuity.

Lessons for nanomedical products to which the existing EU medical products regulation system does not apply

2. The regulatory process of the ATMP Regulation indicates that harmonised regulation is advantageous for all stakeholders involved (Kent et al., 2006). The evaluation of the situation before the establishment of this Regulation shows that the different authorisation standards of the member states were detrimental for consumers (availability and safety problems), but also for industry and the EU itself (problems with regard to creating strong integrated markets).

3. To benefit from potential advantages of regulatory hybridisation, the case study shows that there is room for co-regulatory activities with regard to standardisation and implementation activities, which new nanomedical regulation can use according to the lines set out and modified in more than forty years of EU drugs regulation.

4. With regard to new nanomedical borderline products, the ATMP regulations indicate a tendency to use the pharmaceuticals regulatory approach generally and independently from the product's principal mode of action and to integrate components of other relevant regulatory approaches (such as the medical devices approach).

A final conclusion is that our case study also provides a general lesson for nanotechnological products regulation. Although the characteristics of nanoproducts and industries, as well as the consumers' product reception and ethical problems, are different in other application fields, our case study indicates that the centralisation of knowledge on product safety, quality and efficacy and the coordination of vigilance information are essential to cope with the uncertainty, complexity and ambiguity of nanoproducts risk problems. Centralisation of knowledge and regulatory power, however, call for more democratic controls. It remains to be seen how effective the accountability and transparency measures of the EU ATMP regulations are in practice. Learning from the experiences with pharmacovigilance, as well as from the drug system central risk management and its accountability problems, could support the sense of 'getting it right this time, and from the very beginning' that has been observed by influential commentators in nanotechnological governance (Macnaghten et al., 2005; Krupp and Holliday, 2005; Kearnes and Rip, 2008).

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Part 2. The Dimension of Innovation

Chapter 5. Access to New Technology. In Defense of the Liberal Regime of Innovation

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Abstract
Modern societies should not fall back behind the level of reflexivity they have reached through applying the precautionary principle and engaging in comprehensive technology assessment. But they should beware that the increase of reflexivity does not automatically trigger the increase of restrictions. In view of what new technologies can contribute to the viability and sustainability of society, some of the existing regulations seem counterproductive. A proper balance between control and release of innovations would include a return to precautionary policies that are based on principle and rule, a commitment to experimentation within and with society, and a containment of moral fundamentalism in dealing with human nature. Innovation is bound to be contested and politicized. We should, however, adopt a modest (and realistic) vision of what the state can do to manage the evolution of technology, and leave some space for a private right to innovate that grants individuals and minorities a license to expose society to some degree of 'creative destruction' – even without informed consent.

5.1. Introduction: Resistance against New Technology then and now

In the year 1403, the Council of the City of Nuremberg issued a ban on a new machine for producing steel file and took an oath from the inventors that they would demolish the machine and 'not practice this art again and also not teach it to any person, as long as they live'.[1] The Council suppressed the machine because it was a threat to the existing social order, in this case the medieval guild system of craft production. They considered technological innovation as a subversive activity and accordingly sanctioned it as socially and politically deviant. One would expect that nothing of this sort could happen today. The textbook interpretation is that innovation is a key feature of modern culture and 'adaptive upgrading' (Parsons 1966) and the growth of 'material culture' (Ogburn 1922) are built-in trends and legitimate goals in society. But read Section 63 of the Austrian Gene Technology Act of 1994, according to which genetically modified products must be forbidden if they 'lead to a burden on the society or on social groups (...) which seems unacceptable for macro-economic, social or ethical

[1] '(...) dieselbe kunst iemer ueben und auch das nyemant leren, die weil sie leben' (Wissel 1974, 313).

reasons'. The signal this law sends seems not far removed from what the Council of Nuremberg decreed five hundred years ago. The difference is, of course, that in 1403 the resistance to new technology was part of the long political and cultural battle to preempt the rise of a liberal regime of innovation, whereas in 1994 it was part of a growing disenchantment with the implementation of such a regime.

5.2. The Liberal Regime of Innovation

Policies to suppress new technology have rarely been a lasting success – even in the Middle Ages. In the 16th century the Council of Nuremberg struggled again with unwanted new water mills built by the inventor Hans Speichel. This time the Council stopped the use of the mills by paying the inventor an annual pension in return for his obligation to refrain from his art and for the rest of his life make no other design or prototype of a mill.[2] From the 17th century on the dams broke down in Western Europe. The emerging modern societies implanted a bias in favor of innovation through three structural changes.

1. They institutionalized objective science, which sets the inquiry of nature culturally apart from religious, moral, and political commitments, and thus paves the way for the intellectual pursuit of the growth of knowledge for its own sake. Objective science considers correct experimental prognosis as truth criterion and thus accumulates knowledge that can easily be converted into technology.

2. They turned to capitalist market economies, which are based on imperatives of growth and hence imbue the society with an insatiable thirst for innovation. Since then, the economy provides a permanent opportunity structure for translating new technological options into social practice – in addition to the military and civil engineering demands of the nation states and the chronic need of the medical profession to improve its performance.

3. They established the rule of law and a legal system of basic rights, which imply a right to introduce new technology and to have access to it, on the level of both institutions and individuals.

These structural changes 'disenchained' the productive forces of technology (to borrow the phrase from Karl Marx) and limited the power of the state to regulate innovation. Above all, the growth of options slipped completely from state control. New technologies spring

[2] '(...) seins handwergs zu warten (...) und sein lebenlang kein handwergs oder anderer müelwerg vizier und muster zu machen' (Wissel 1974, 315).

from knowledge systems that function on the level of the world society. Knowledge travels easily across national borders; local inventions become globally available as information. States can still regulate the use of options, but they must balance such regulation with guaranteed freedoms. Innovation is not a privilege that can be granted or withheld at will by political authorities; it is a civil right that can only be restricted for reasons of compelling public interests. Evidently, risks to important private and public goods, such as health and environmental safety, or violations of the accepted moral order constitute sound reasons for restricting the use of new technology. However, the burden of proof is with the regulatory agencies. Reasons must be substantiated by those who want to block access to options, not by those who claim access.[3]

Modern societies install a liberal regime of innovation. They set some boundary conditions for the use of new technology but leave the evolution of the technostructure to a large extent to social forces – to markets, professions, entrepreneurs, consumers and clients.

5.3. A License to Expose the Society to 'Creative Destruction'?

Technological determinism is an ill-conceived philosophy because the rise of a technology is no doubt a social process. It may nevertheless be a good description of what actually happens. The liberal regime places innovation beyond political control. It amounts to a license to expose the society to 'creative destruction'.[4] This destruction may be far-reaching: industries collapse, job qualifications and social competences of people become obsolete, cultural values are challenged. It is an underlying rationale of the liberal regime that the benefits from innovation are worth the price of creative destruction, and that society is better off by addressing the task of coping with the consequences than by suppressing the innovation in the first place.

The liberal regime of innovation has never gone uncontested. Resistance against new technology has been endemic throughout the history of liberal societies. It mostly failed. In 1986, trade unions in London mobilized 5300 printers in a strike against the introduction of electronic printing and desktop publishing by journalists in their newspaper company. The only thing they achieved was that old printing houses were shut down by the owner, who then opened an electronic

[3] Under German constitutional law, a 'principle of proportionality' applies that forces authorities to prove that regulatory measures are suitable for the public purpose, are the least restrictive alternative available, and do not put excessive burden on citizens.

[4] This is how Joseph Schumpeter characterized 'the process of industrial mutation (...) that incessantly revolutionizes the economic structure *from within*, incessantly destroying the old one, incessantly creating a new one (...) the perennial gale of creative destruction' (1975: 82-83).

business next door with only 1300 personnel.[5] In the end, all parties somehow managed to accommodate themselves to the innovation. In some cases, however, particularly with genetically modified crops and food, the introduction of new technology has effectively been blocked in Europe by political regulation in response to popular unease and protest. Whether these cases are an exception or a model remains to be seen. The liberal regime of innovation is acknowledged in the rhetoric of politics and law. In public opinion it is less clear that private freedom to operate should indeed be considered a sufficient and legitimate ground to expose society to the 'creative destruction' of technological change.

The very concept of freedom implies that beyond the evident limits of respect for the moral order and the duty of doing no harm, one can impose consequences on others without being held responsible. Freedom to reproduce means that individuals who choose not to have children cannot be held responsible for the problems of demographic change to which they contribute and with which society then must struggle. People do not, however, readily accept that such limits of responsibility should also apply when multinational corporations place genetically modified crops or products of nanotechnology on the market, when medical professionals apply drugs to dope the intellectual or sexual capacities of their clients, or when scientists produce tissue for human transplantation from embryonic stem cells. In these cases, there is growing support for policies that relegate the freedom to innovate from the catalogue of guaranteed civil liberties and turn access to new technology back into a public concession rather than a private right. A tendency to retreat from the liberal regime of innovation manifests itself in certain interpretations of the precautionary principle, in demands for sustainability and social responsibility of innovation, and in moral verdicts against intervening in human life and the body.

5.4. Precaution without a Principle

The liberal regime of innovation operates with a presumption of 'in dubio pro libertate'. However, in recent conflicts the precautionary principle has become a means to dismantle this presumption. Under the precautionary principle, regulatory authorities may impose preventive restrictions if there is still 'lack of full scientific certainty'

[5] A similar failure was the effort in the 1980s to ban the use of personal computers in university offices in Bremen to ensure that it remained the domain of secretaries to write scientific manuscripts – on typewriting machines. After a short while, the secretaries themselves wanted the computers.

about the existence of suspected risks.[6] Critics of new technology have read this as implying that uncertainty about the existence of risks should be taken as indicating the possibility of risk. And they have successfully used tactics of escalating such uncertainty to postpone the authorization of new technology indefinitely, for example, in the case of genetically modified (GM) crop varieties.

Part of the tactic is the de-construction of the knowledge claims of scientific risk assessments. Such assessments derive statements about the likelihood of adverse effects on human health or the environment from the results of toxicological, ecological or clinical testing. They reflect the given state of knowledge about what possible risks might be and about the causal mechanisms through which they might lead to harm. They rely on testing procedures that investigate a limited number of parameters in model systems and make projections which are, in principle, falsifiable. Such assessments have obvious limits. They cannot exclude the possibility of false negatives, i.e., wrongly finding that no harm is to be expected. And they cannot address hidden or unknown risks which we may have never seen and cannot anticipate in testable hypotheses. These limits confront us with uncertainties that 'encircle the science rather than being encircled by it' (Wynne and Mayer, 1993: 33). Critics expose these limits to denounce regulations that authorize new technology if it passes the tests of scientific risk assessment as 'uncertainty blind' and insufficient under the precautionary principle (Van Asselt and Vos, 2008: 290). In addition, they occasionally invoke an epistemology of social construction of knowledge to undermine the trustworthiness of scientific risk analysis further.[7]

If the uncertainties that 'encircle science' constitute sufficient reason to suspect the existence of risk, then scientific analysis is effectively removed from the agenda of risk regulation under the

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[6] The precautionary principle is, e.g., expressed in principle 15 of the Rio Declaration on Environment and Development (1992) as follows: 'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation' (UNCED, 1992: 10). Another version has been implied as a binding rule under international law in the Cartagena Protocol on Biosafety (2000): 'Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account the risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism (...) in order to avoid or minimize such potential adverse effects.'

[7] 'The reality in science, as in nearly any other field of knowledge, with the possible exception of some branches of the natural sciences is socially constructed' (Christoforou, 2003: 208).

precautionary principle.[8] At the same time, the cautious reversal of the burden of proof imposed by regulations that authorize new technology only if no adverse effects are to be expected is turned into an insurmountable obstacle for those who seek authorization. While testable hypotheses about possible adverse effects can eventually be refuted, it is impossible to refute suspicion of risk based on uncertainty alone.[9]

This interpretation leaves no space for a right to innovate. The same follows from claims that in the case of uncertainty about the effects of new technology, worst case scenarios should be accepted as plausible hypotheses. Such claims remove the constraints that the principle of proportionality can impose on the regulation of uncertain or unknown risks. If one must assume 'that the unexplored risks could be far greater than risks for which we have empirical evidence',[10] one cannot possibly ignore such risks under a *de minimis* clause or balance them with expected benefits; rather they have to be excluded under all circumstances.

Radical interpretations of the precautionary principle shift the basis of regulation from the scientific assessment of risk to the public perception of risk. Theofanis Christoforou openly advocates that 'risk managers instead of trying to patronize consumers with positivist views on science should take into account their legitimate concerns and the public perceptions of risk' (2003: 208). The European Commission has occasionally followed such 'advice'. In the case of the ban on beef from cattle treated with growth hormones, it dismissed pending scientific assessments and, according to Advocate General Lenz, gave 'reference to the interests of consumers, because it could be seen that meat from animals treated with hormones was widely rejected' (Joerges, 1997:309). If regulation relies not on the existence of risk but on the perception of risk, it is besides the point to require risk comparison in order to ensure consistent rule-making. Risk perception is selective and it is contingent upon factors such as familiarity, institutional trust and feelings of injustice. These conditions fluctuate in cycles of protest and attention. People fear crops from GMOs, but

[8] Proof of uncertainty is all what is needed. This point is made by Theofanis Christoforou, a legal expert to the European Commission, who claims that the precautionary principle is still 'firmly based on science, because its application is warranted only when uncertainty is scientifically established' (2003: 210).

[9] Van Asselt and Vos cite the uncertain risks of GMOs as a case in point: 'scientific or historical evidence of harmful consequences are lacking, but suspicions cannot fully be refuted either' (2008: 281).

[10] An assumption held by Murswiek 1985, 214, and some other renowned legal professionals in Germany in the 1990s (discussed in Van den Daele 1999, 267). See also Peterson, 2007: 308: 'The consequence of falsely believing [a new substance] to be safe might be catastrophic'.

they do not fear crops from conventional breeding techniques – notwithstanding that the latter may equally be encircled by irresolvable uncertainties about long-term or synergistic adverse effects which are yet unexplored and unknown and which may even be unknowable in principle. When risk perception is enough to warrant precautionary restrictions, regulatory agencies enjoy maximum discretion to grant or refuse access to new technology in an ad-hocracy of decision-making that follows political expediency or opportunity. Then, indeed, 'all the substantive and procedural constraints on regulatory arbitrariness are relaxed to the point of becoming non-binding' (Majone, 2002: 101). Under such interpretations of the precautionary principle, innovation is a public concession, not a private right.

5.5. Protecting the Status Quo: Social Sustainability as a Criterion

The politicization of innovation is further strengthened by the tendency to conflate the management of risk with concerns of technology assessment. Technology assessments consider a broad spectrum of gains and losses which might be ensuing from an innovation, including impacts on human health and environmental safety as well as on social, economic, political and cultural domains. They indicate the rise of a more reflexive attitude towards technological growth in the last decades. And they often strike a sceptical note because they give particular voice to critical concerns that would not be put on the agenda by the proponents of new technology. The incorporation of such concerns into the risk regime is bound to lead to more restrictions.

Thus, in a report prepared by the European Science and Technology Observatory network for the European Commission, it is argued that the appraisal of the technological risks of genetically modified crops should take into account socio-economic impacts and social needs such as the welfare of small farmers, exports of developing countries, employment, and quality of life (ESTO, 1999: 10). Precautionary risk regulation should consider whether we need the proposed innovations or have alternative (better) options. The comparison should include aspects of fairness: 'To what extent do the distribution of burdens imposed by different options act to alleviate or compound pre-existing patterns of privilege or social disadvantage?' (ESTO, 1999: 11).[11]

Such claims have occasionally been enacted in regulations. A case in point is the above-mentioned Section 63 of the Austrian Gene Technology Act of 1994, which forbids products of genetic engineering which can 'lead to a burden on society or social groups which cannot

[11] Notions of justice play a role in risk perception, see Rayner and Cantor, 1987.

be compensated, and if the burden on the society appears unacceptable for economic, social or ethical reasons'. Section 10 of the Norwegian Gene Technology Act of 1993 similarly requires 'that in deciding whether or not to grant the application significant emphasis shall be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development'. The Danish government has promised an effort to include ethical criteria into European and international regulation that would make the authorization of GMOs contingent upon the equal distribution of burdens and benefits in the society.[12] The Commission of the European Communities has officially distanced itself from the application of socio-economic need as a criterion for the authorization of new technology.[13] However, it has tacitly adopted the criterion in its regulation of beef from animals injected with human growth hormones. And it has opened the door further in recent regulations on food safety by declaring that risk management decisions can legitimately be based on economic, societal and traditional factors.[14]

This regulatory philosophy dismantles the liberal regime of innovation. Innovation becomes a matter of democratic rule and public planning rather than of private choice and market forces. The underlying assumption is that the state has the mandate and task to decide whether an innovation is welcome and that the legitimacy of new technology is contingent upon broad public acceptance – or at least majority approval. This approach is biased towards the protection of the status quo. The fact that an innovation may trigger resistance and conflict becomes an argument against it. Ortwin Renn argues that in the case of complex, uncertain or ambiguous risks, the risk appraisal should be based on an assessment of social consequences, such as concerns of people, the escalation of risk perceptions and the rise of mistrust in regulatory agencies (2008: 67-74).The ESTO Report even

[12] 'Genetic engineering must be used in such a manner that it does not conflict with our efforts to create a society where benefits and burdens are distributed equitably. This consideration applies both within the individual society as well as with regard to fostering sustainable development in relation to other countries, including developing countries, and in relation to future generations' (Danish Ministry of Trade and Industry, 2000: 11).

[13] 'By their nature, socioeconomic aspects need to be considered in a different way. It is not intended to have included another systematic assessment in addition to the three criteria [of safety, efficacy and quality]' (EC 1991, conclusion).

[14] Recital 19 Regulation (EC) No 178/2002: 'It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.' See also Christoforou, 2007: 209.

requires that 'disruptive changes to normal routines and attitudes' involved in new technological options must be taken into account (1999: 11). Under such criteria, conventional technologies to which people and institutions have already become accustomed are likely to fare better than innovation.

5.6. The Return of the 'sacred' in the Regulation of Technology: Human Nature as a Holy Order

The liberal regime of innovation has not only come under pressure from rising expectations of risk avoidance and quests for democratic control of technological change. It is also challenged by claims of moral respect for nature. Human nature, in particular, is invoked as a moral order that must not be undermined through technical intervention.

Within the framework of modern science and technology, the natural world is conceived as devoid of intrinsic moral qualities. Nature is not a meaningfully ordered cosmos to be treated with humble respect but rather, as Francis Bacon put it in the early 17th century, a 'storehouse of matters' open to serve human purposes (1620: 225). Bacon, accordingly, dismissed the suggestion 'that the inquisition of nature is in any part interdicted or forbidden' as superstition (20). René Descartes similarly anticipated that we will make ourselves the 'masters and possessors of nature' (1637: 51). At the same time he exempted the essence of human being from such mastery and possession by placing the subject as a mindful and moral agent (*res cogitans*) categorically apart from the natural (*res extensa*). This dualism has always raised doubts. It seems untenable today in view of the fact that modern biology and biotechnology are deeply affecting our notions and images of what it means to be human by creating options for genetic manipulation, organ transplantation, combinations of the body with machines, new modes of reproduction, pharmacological modulation of emotions, and interventions in the brain. We are heading towards a situation in which it becomes literally true that 'Man makes himself'; but in contrast to what Gordon Childe (1958) had in mind, this occurs not by shaping the cultural environment but by reconstructing human nature through technical interventions.

This perspective provokes strong moral reactions that not only (and not primarily) aim at the protection of basic rights and avoiding possible social harm, but that claim respect for the naturalness of human beings. Deviations from the course of nature, from natural ways of giving birth and of dying, from natural genomic recombination, from natural processes of aging are considered violations of the moral order, because they are dehumanizing practices and incompatible with human dignity.

Reproductive cloning is widely considered to be a prime example of a 'dehumanizing practice'.[15] Other techniques that raise a moral verdict are surrogate motherhood, sex selection of offspring, sperm or egg donation for artificial insemination, prenatal genetic diagnosis, immunological matching of a prospective child for lifesaving treatment of a sibling, germline intervention, animal organs for transplantation in human patients, research with human embryonic stem cells, enhancement of mental, emotional or sexual capacities through neurophysiological or pharmacological modulation, or the implantation of electronic devices in the brain.

Some of these verdicts are contested and their social and political impact is uncertain. They may give way if they have to be balanced with legitimate interests and goods. Medical purposes, in particular, have often overcome arguments that the naturalness of human nature is a taboo not to be touched. However, various of these objections have already found their way into restrictive legislation in a number of countries.[16] The battle over moral limits to the technical intervention in human nature is ongoing.[17] What is at stake in these battles is not only the freedom to operate of companies and professions, but also the self-determination of patients and clients who claim that they can choose how to deal with their own life and body. To refute these claims the moral objections are often raised to the highest possible rank of the moral order (*Sittengesetz*) and classified as imperatives of human dignity which by definition must not be compromised by balancing them with concurrent concerns or rights, and which cannot be overruled even by democratic majority rule.[18]

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[15] This phrase is used in the Report of the U.S. President's Council on Bioethics which compared reproductive cloning with incest and – surprisingly – also with polygamy (2002: 86/112).

[16] The list of prohibitions in the German Embryo Protection Act of 1990 includes surrogate motherhood, donation of egg cells or embryos for IVF (in-vitro fertilizilation), IVF after the death of the sperm donor, sex selection in IVF (except in cases of X-linked diseases), prenatal genetic diagnostic, the use of human embryos for research or for creating stem cells, cloning of embryos, changing germ cells that are to be used for reproduction, creating hybrid (man/man) or chimeric (man/animal) embryos or transferring them for reproduction to an animal or a women. For a similar list in the Belgian Law on Research into Embryos *in Vitro* of 2002
see http://www.biopolicywiki.org/index.php?title=Belgium (accessed 26 February 2010).

[17] In 2003 the European Parliament voted in favor of a complete ban of embryonic stem cell research in Europe. The vote was overturned by the European Commission on formal grounds: regulation of research was not at issue in the legislation to which the vote was added. See http://www.futurepundit.com/archives/001130.html (accessed 4 March 2010)

[18] Evidence for such tendency can be taken from scholarly debates in German constitutional law. See, for instance, Starck, 2006.

5.7. Political and Moral Controls of Innovation: Towards a Proper Balance

The politics of precaution and the quest for democratic control of technological change can be hailed as a retreat from the naïve and optimistic 'laissez innover' beliefs of the past and as a transition to a more reflexive, sceptical – and, for that matter, more enlightened – attitude towards the dynamics of technology. Modern societies should certainly not fall back behind the level of reflexivity they have reached through applying the precautionary principle and engaging in comprehensive technology assessment. But they should beware that the increase in reflexivity does not automatically trigger an increase in restrictions. In view of what new technologies can contribute to the viability and sustainability of society, some of the emerging restrictions seem counterproductive. A proper balance between the control and the release of innovations would include a return to precautionary policies which are based on principle and rule, a commitment to some extent of experimentation within and with society, and a containment of moral fundamentalism in dealing with human nature. Reflexivity breeds politicization and conflict. The quest for 'responsible innovation' is now firmly on the political agenda. The challenge is to demarcate and calibrate this responsibility. Restrictive policies are one part of the answer, compensation of unwanted consequences and constructive policies to shape technological change are another part. A modest (and more realistic) vision of what the state can do to manage the evolution of technology suggests, however, that space should be left for a private right to innovate which grants individuals and minorities a license to expose society to some degree of 'creative destruction' – even without informed consent.

5.7.1. Precaution with a Principle: Rules of Law for Administrative Agencies

The expectation that the precautionary principle will grant political discretion to regulatory agencies to authorize or ban a new technology because of perceived risks, public discontent, or the evaluation of social need, has already been dashed by the courts. National jurisdictions and the European courts insist that precautionary restrictions must be based on risk assessment and not on risk perception alone. Risk assessment must use the best available scientific expertise. In case of uncertainty, reasonable concern about possible risks is required; unfounded suspicion of harm or speculative risks which can neither be substantiated nor excluded are not enough, neither is the mere reference to limits of knowledge or epistemic ignorance. The courts have also ruled that proponents of new technology must not be

confronted with burdens of proof that amount to the proof of zero risk or of absence of unknown risks.[19] Court decisions thus restore the role of institutionalized science and objective knowledge as a frame of reference for dealing with claims of risk, and they preempt concessions to relativist epistemologies or social constructivism.[20] They also restore formal rationality by turning the precautionary principle back into a 'rule' of law which provides some legal certainty by committing regulatory authorities to transparent and consistent decision-making, and which precludes unforeseeable and arbitrary *ad hoc* precautions that reflect political opportunism rather than legal rule. The requirements of consistency and non-discrimination have been explicitly acknowledged in the European Commission's Communication on the Precautionary Principle (1999, no. 6.3.2 and 6.3.3). If they were actually adhered to, a precautionary ban on the use of GM crops in agriculture could no longer be based upon unresolved uncertainties about their long-term or hidden potential for harmful consequences, since the same uncertainties hold for new conventionally bred crops as well, and these continue to be allowed. In many countries, administrative discretion is further narrowed by a principle of proportionality which obliges regulatory agencies to lay down that precautionary measures are effective and necessary, i.e., that they are suitable to reduce suspected risks and that no less restrictive alternatives are feasible. The constraints imposed by the courts leave ample space for preventive controls of the potential risks of new technology. But they define conditions under which the proponents are entitled to the authorization of new technology and thus confirm the freedom to operate, in principle. Under such jurisdiction the precautionary principle is an amendment to the liberal regime of innovation rather than a substitute for it.

5.7.2. Non-discrimination and Risk Comparison in Precautionary Law-making

The constraints that limit the discretion of regulatory agencies in applying the law do not necessarily hold for making the law. Administrators who apply the precautionary principle as a legal rule in authorization procedures or standard setting cannot freely choose

[19] For the European courts, see Stokes, 2008; Van den Daele, 2008a.

[20] See also Joerges, 1997: 320. Consequently, there is no space for a democratization of risk assessment through the participation of stakeholders and lay people. The establishment of knowledge claims, including claims of what is uncertain and what is unknown remains the prerogative of expert communities. Public participation can raise questions, but not determine the answers; the proper domain for it is management of risk, not risk assessment.

precautionary restrictions of new technology. Legislators can.[21] Parliaments can restrict even in the case of unfounded suspicion of risk, and they can do so selectively responding to cycles of risk perceptions and protest in the public opinion. The question is: should they? A well-reasoned approach to precaution would not only take into account that fear and mistrust of the public can be fabricated and hence responsive policies may in fact be captured by protest movements (see also Charnley and Elliot, 2002: 10366). It would also consider the costs of restricting new technology just because there remains uncertainty about its possible risks. There is no reason to embrace the romance of the zero option and believe that we are likely to be safe rather than sorry if we renounce innovation. The ban on GM crops promises protection against possible environmental or health risks which we have not yet seen and which may or may not exist. It does not preserve an idyllic natural state; it rather keeps us stuck with familiar technologies which are likewise laden with uncertainties about possible future impacts and in fact may already have caused problems in the past. It is irony and political pathology that in the movement against GM crops, conventional agriculture comes out as the 'good guy' that has to be protected, in coalition with organic farming. That deflects from the severe environmental problems caused by this type of agriculture and from the fact that it urgently needs innovation. Properly balanced precautionary policies must consider the gains and losses of restricting innovation. That includes comparison of the risks (and uncertainties) of new and old technologies.[22] The REACH approach adopted by the European Union in the control of chemicals meets this requirement by comparing new substances with the ones already on the market which they could replace. The GM regulations fail this test.

They also fail the test of consistent rule-making. Regulations ban GM crops on grounds which, when applied as a general rule, would exclude conventionally bred crops as well. However, with new conventional crops the limited testing applied by breeders to identify unwanted or harmful effects is accepted as sufficient ground to consider such crops as safe for being marketed, although the testing

[21] German Courts have affirmed the power of parliament to restrict the private right to keep certain dogs for the reason that they are widely perceived as being particularly dangerous and lack acceptance, see Bundesverwaltungsgericht, Entscheidungen 110, 265 (Judgement of 19 January 2000). Hood et al., 2006 cite the British Dangerous Dog Act as a case where media agitation and responses to tragedy have induced ad-hoc regulation which can be criticized as 'knee-jerk' policy on the hand, but must also be acknowledged as opinion responsiveness in democratic government on the other (182-183).

[22] They must also recognize trade-offs between risks avoided by restricting new technology and risks caused by the restrictions; see the recent debate over such trade-offs in the *Journal of Risk Research*: Hansen et al., 2008; Graham and Wiener, 2008.

clearly cannot resolve all uncertainties which 'encircle' such crops. With GM crops, in contrast, no amount of testing is considered sufficient.[23] Inconsistent law-making also prevails in initiatives to deny the authorization of GM crops if they negatively impact the biodiversity in agriculture, the social conditions of small farmers, or the exports of developing countries. The impacts GM crops could possibly have in these respects appear marginal compared to the devastation caused by the modern system of industrialized agriculture anyhow. Conventionally bred high yield and hybrid crops play a major part here, but it was never envisaged to ban them for that reason. Rather, in their case, it is accepted that such problems must be dealt with through regulation of good agricultural practice, programmes for rural development, or antitrust law. Sheer hypocrisy prevails when European governments advocate the exclusion of GM crops because they violate social justice in jeopardizing the prospects of developing countries to sell their agricultural products on the world market, while they at the same time uphold protectionist policies that keep such products out of Europe.

5.7.3. New Technology and the Common Good

Precautionary policies that ignore the requirements of proportionality, risk comparison and consistent rule-making and respond instead *ad hoc* and selectively to cycles of public fear and mistrust are bound to operate against innovation and to affirm the technological *status quo* of society. This would be nothing to deplore if there was reason to believe that we can solve our problems with the technologies we already have. Unfortunately, that is not the case.

Modern societies depend on technological innovation, not only to keep pace in economic competition, but also to achieve broader goals of the common good and solve major environmental and social problems like climate change, water and energy supply, health care, and food production. While, in theory, many problems could also be solved through radical social and political reform, in practice such reforms are often not feasible, and technological fixes which are compatible with existing socio-political structures may be the only solution. With regard to food supply it should also be considered that rigorous redistribution of available resources (which is, however,

[23] The standard justification for the discrimination against GM crops is that the techniques of genetic modification are new whereas we are familiar with conventional breeding. However, smart breeding is also new, but does not meet the same resistance as GM crops. In Germany, it has even been welcomed by representatives of the Green Party as an alternative to GM crops. Since smart breeding relies on mobilizing plant genes which may never have been functional in the plant, it seems that the true reason for the resistance against GM crops is the fact that it introduces 'foreign' genes into the plant. This philosophy of genetic purity is hardly politically correct and difficult to defend openly.

unlikely to happen) might suffice to feed the world today. In a few decades, with the world population having increased by two billion, it will be impossible to avert mass starvation without dramatic increases of crop productivity. While nobody can assure us that GM crops will in fact make a significant contribution, it is neither possible to promise that the breeding techniques we applied in the past to increase crop productivity will also do the job in the future. Given these uncertainties, it seems unreasonable to forego any of the available technological options (unless one has grounds to assume that they are really harmful).

Rational policy would promote technological pluralism and support the introduction of new options rather than homogenize society's resources by building protective belts around established techniques to which we have already adapted. Complex systems preserve their viability not only through the continuity of their basic structures but also through the introduction of structural variants which prepare them for adaptation and make them 'resilient' to fluctuating environments. This holds for natural ecosystems; it also holds for societies.[24]

5.7.4. Proceed with Caution, but Proceed!

'Look before you leap!' (ESTO 1999, 22) is sound advice. Policy-makers should be aware that new technologies are fraught with uncertainties about possible or hidden risks. But they should think twice before seeking safety by prohibiting the technology for that reason. We may lose more than we gain. There is truth in the warning of Aaron Wildavsky (1979) that no risk may be the highest risk. To a certain extent the introduction of new technology amounts indeed to an experiment with society, the outcome of which is not and cannot be known in advance. However, instead of avoiding such experiments altogether it seems more advisable to design them properly and use some of the learning mechanisms that apply in controlled experiments in the laboratory. Such 'experimental implementation' requires, for example, that new technologies are introduced step by step, with documentation and monitoring to warrant early detection of unexpected potential for harm. [25] One could also embed innovations in a culture of safety by holding those who promote them liable for unexpected harm cause by the new technology and by obliging them to seek insurance. These measures should not be used as tactics to make the technology unfeasible. They should strike a balance of optimizing protection against undetected risks while at the same time preserving

[24] See Holling 1973 for the distinction between 'stability' and 'resilience' in ecosystems.

[25] See Van den Daele and Krohn 1998, for the notion of 'experimental implementation'; technological innovation is conceived as 'Realexperiment' (real-world experiment).

the space for innovation. The keeping of such a balance is in line with the legal principle that proportionality is required when rights are restricted.

5.7.5. Compensating for Unwanted Consequences as a Policy Option

In designing 'responsible innovation', policy-makers must take the lessons of technology assessment into account that innovations are a mixed blessing, in the sense that they will have unwanted consequences and that they produce losers in society. They should, however, also consider that except in the cases circumscribed by a properly defined precautionary principle and the accepted rules of the moral law, compensatory rather than restrictive policies may be in order to address the problems. In fact, most existing regulations of second-order consequences of new technology do not try to prevent such consequences in the first place but provide some compensation for them. Thus, labor market policies and educational training programmes try to compensate for the losses of jobs and qualifications caused by competition from new products or new modes of production. Information and counseling services are offered to help people to retain their autonomy in view of the disturbing choices presented by new options to intervene into the human body and life.[26]

5.7.6. Dealing with Human Nature: Moral Rigor vs. Trust in People

The furor occasionally displayed in debates over the moral boundaries of intervening in human nature seems rather misplaced. To be sure, legitimate innovation must comply with the basic moral order that is reflected in the broad consensus of the people and, as a rule, embodied in the books or traditions of constitutional law. However, most of the moral claims invoked against applying modern biotechnology to humans lack consensus. People do not agree whether it is morally admissible to do research on human embryos or to perform tests on them before implantation or to allow manipulation of germ cells. Such disagreement is rational dissent, because it exists despite endless efforts to resolve the disputes through moral analysis and argumentation. The common ground of reasons which all parties find

[26] In Germany, Hoffmann-Riem, then a judge at the Supreme Court (Bundesverfassungsgericht), argues that responsibility for innovation implies that tests of 'orientation towards the common good' and 'social compatibility' are met (2006: 267). He also derives basic requirements of these tests from constitutional norms of distributive justice (equality of chances and provision of factual conditions under which people can actually make use of guaranteed freedoms). Such notions of responsibility will amount to severe restrictions of innovation – unless it is emphasized that innovation is itself a common good and that there is a broad political discretion to opt for compensatory rather than restrictive responses in dealing with unwanted or unjust consequences.

convincing is insufficient to decide the issues. We have moral pluralism in society. People are split regarding the moral rules, just as they are split regarding religious beliefs.

Awareness of the moral pluralism that exists in society should operate against self-righteousness and fundamentalism in moral debate. One cannot credibly separate the good from the bad in these debates and excommunicate, so to speak, dissenters from the moral community by labeling them as insane, criminal or incompetent.[27] As a consequence, collectively binding regulations of the contested issues must be shifted from the moral to the political domain. They cannot and should not be based on the affirmation of the moral order, but only on the legitimacy of democratic majority rule.

We are still far from generally accepting that many of the moral issues surrounding human nature are political questions that can legitimately be decided one way or the other. It is often tried to make restrictive positions morally compelling by projecting that a less restrictive standard would have serious negative consequences for society. Such arguments relate to the common moral ground of doing no harm, but they rarely proceed to the test of whether such consequences are in fact to be expected. This is ritualism in moral argument, which should be overcome.[28]

In view of moral pluralism, regulations that invoke absolute limits by associating the integrity of human nature with the dignity of man and placing it beyond compromise with other values are unacceptable. They ignore the costs of moral rigorism. Respect for human nature is a legitimate concern; it should, however, be balanced with the prospects of patients who hope that new and more technical interventions in the body will relieve them from suffering or save their lives. And it should also be balanced with the right of the people to decide themselves how they want to deal with their own body, according to their own vision of the pursuit of happiness. Moral rules that protect human nature against technical interventions reflect a deep mistrust in self-determination. People are suspected of being irrational, superficial, and easily seducible, or to be in the grip of subtle but irresistible external influences ('biopower' in Michel Foucault's term) that deflect them from an authentic human life. However, the value system of modern societies provides no cogent reasons to restrict human rights in order

[27] Comparative legal analysis should have the same effect; see, e.g., for embryo research in Europe, Solter et al., 2003. For rational dissent and moral pluralism in the German National Ethics Council, see Van den Daele, 2008b.

[28] For example, in the case of euthanasia and physician-assisted suicide for patients with incurable diseases, projections of a disastrous decline in the valuation and protection of human life are quite common, but their proper investigation is avoided, see Van den Daele, 2008c.

to protect notions of what it means to be really or authentically human. Regulations that pursue such protection tend to be paternalistic – either exerted by the majority over minorities in society or by cultural elites over the allegedly uneducated masses.[29] It seems more appropriate to empower people by helping them to make their own decisions rather than disenfranchise them by depriving them of the right to choose. Then we must, by implication, accept that the future of the human nature and the notion of what it means to be really human will evolve with the choices people make.

5.8. The Private Right to Innovate in a Reflexive Society

The quest for 'responsible innovation' turns the decision whether or not to introduce new technology into a matter of state policy and public choice rather than of private freedom to operate. Who should decide which innovation is welcome? Is there a role left for a right to innovate?

Many observers advocate stakeholder participation to cope with conflicts over new technology (Renn, 2008: 273). This can hardly be the solution. Deliberative procedures, such as consensus conferences, citizen juries, focus groups, and deliberative polls (ESTO, 1999: 36) may build public trust by giving voice to the opinions and beliefs of the people. And they may somehow ease conflicts with stakeholders – as long as they postpone decision-making to resolve the conflict. But they amount to inconclusive or empty proceduralism if they serve as mere sounding boards for diverging views and beliefs which are left to stand as they are. On the other hand, it is seems impossible to empower stakeholder participation with a mandate to negotiate collectively binding conflict resolutions. Such corporatism lacks not only democratic legitimacy; it also leads to blockades, since it is likely to be captured by veto players who want to postpone the decision indefinitely. The demarcation of responsibility for innovation must reside with the state. This does not imply, however, that the state can or should be entrusted with a mandate for comprehensive planning of innovation.

Modern states reach beyond restrictive or compensatory policies and involve themselves actively in constructing and shaping the frontiers of technology. One should, however, be realistic about what they can achieve in this respect. States can provide opportunity structures for technological options, for example, by supporting certain lines of research and development, by subsidizing market entrance or

[29] Euthanasia is a case in point for the latter. While up to 70% of the people in liberal societies believe that it should be allowed, parliaments, courts, representative professional bodies and influential mass media continue to support existing bans.

by granting tax incentives. But in most constructive policies, states are co-players in the game of innovation, not masters of it. Apart from the cases where they have a monopoly for demand or supply, as in military or public infrastructure networks, they cannot and should not exert total control over the social drama of innovation. From a normative perspective it is not the mandate of the state and of majority rule under a liberal legal constitution to determine how people should conduct their lives. Whether a new technology is meaningful or worthwhile to pursue and whether 'we want to live with it' remains a matter of private freedom. It is not for parliaments to decide whether we need computers or mobile phones or in-vitro-fertilization or cosmetic surgery, or have better alternatives – just as they cannot decide whether we should marry or have children or get divorced. From the perspective of efficacy, there is no reason to believe that states can mobilize the imagination and flexibility needed to create the pool of innovations that will satisfy the aspirations of the people and sustain the resilience of society in fluctuating environments.

Political planning can be a supplement to the societal forces of innovation, not a substitute for them. Increasing reflexivity and politicization of the dynamics of technology have induced profound changes in the liberal regime of innovation. But they have not rendered the right to innovate obsolete. We still need the challenges of the *status quo* that come from the freedom of scientists and engineers or professionals and clients and entrepreneurs and consumers who expose society to creative destruction through new technology from a minority position – even without informed consent.

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Chapter 6. Patenting Nanotechnology: Are We on the Right Track?

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Abstract
Nanotechnology – the technology that brings the atom-by-atom manipulation of matter within reach – holds out the promise of many societal benefits, such as dramatic progress in healthcare, environmental benefits and further advances in computing. Patents will be of crucial importance if innovation in nanotechnology is to live up to the expectations. However, the large number of patents granted for nanotechnology and the basic character of some of these patents may also hinder the realisation of this potential. Impenetrable patent thickets or patents with great blocking power may be created. This chapter investigates whether patent law is being appropriately applied with a view to realising the full innovative potential of nanotechnology and its societal benefits. It will not deal with the question of whether nanotechnology is patentable *per se*, but will focus on the way in which patents are currently being granted.

6.1. Introduction

Nanotechnology is the technology of the smallest objects. It holds the promise of manipulation on an atom-by-atom basis and represents the ultimate control over matter. The European Patent Office (hereinafter: EPO) defines nanotechnology as follows (Kallinger, 2007):

> "The term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100 nanometres in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size. It covers equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100 nanometres."

Potentially significant societal benefits are in the offing. In healthcare, nanotechnology could bring about advances such as the selected targeting of cancer cells or the creation of clean drinking water from contaminated supplies in developing countries. For the environment, nanotechnology could bring benefits in relation to fuel saving additives, more efficient production of solar cells, cleaner generation of hydrogen, faster charging rechargeable batteries and better insulation of buildings (Walsh, 2007). In computing, nanotechnology promises even smaller chips and with higher memory capacity. It is anticipated that many new

products will be developed on the basis of nanotechnology and that the quality of existing products may be vastly improved (Pen, 2009). However, the benefits of nanotechnology will only materialise if laboratory results can be adequately translated into innovations leading to new products and services on the market.

Patents traditionally play an important role in stimulating innovation. There is no doubt that inventions in the field of nanotechnology can be protected by patents (Bowman, 2007; Newberger, 2003). However, certain developments indicate that patent law is not being used in a manner that extracts the most from the innovative potential that nanotechnology offers. Concerns have already been voiced that patents are being granted on the building blocks of the technology, such as relatively simple molecules (Lemley, 2005; Zekos, 2006b). If these concerns are justified, some patents in nanotechnology would be very valuable but they would also have an enormous potential to block the research of others. The same holds for patents on the underlying principles of nanotechnology. They too would afford too much power to pioneering innovators and upstream researchers. The eagerness to patent nanotechnology also raises concerns about the number of patents. Using its wide definition of nanotechnology, the EPO has identified about 108,000 patent documents relating to inventions in the field of nanotechnology (Kallinger, 2007). The existence of so many patents in the field of nanotechnology could also serve to hamper downstream innovation. These concerns are not as yet empirically validated. This chapter will show, however, that nanotechnology itself possesses a number of characteristics that give credence to the concerns raised. Although this does not amount to proof of a problem, it will be argued it amounts to sufficient reasons for concern. This chapter further argues that the risk is serious enough to consider the taking of certain intra-systemic steps to ensure the appropriate functioning of the patent system so that society is better placed to reap the fruits of nanotechnology. Where possible, analogies with biotechnology are drawn. Biotechnology has seen a relatively recent scientific and technological growth, and it has experienced very similar problems with respect to patents that nanotechnology currently faces.

The outline of the chapter is as follows. The second section shows in what respects nanotechnology differs from previous technologies and what adverse implications this may have for innovation. In the third section, a number of avenues for addressing the issues mentioned in the second section are identified.

6.2. The Uneasy Relationship between Nanotechnology and the Patent System

The patent system is designed to spur innovation. Nanotechnology has, however, some characteristics that hinder the patent system in stimulating innovation. I will consider here three characteristics in particular. In the first place, nanotechnology is science based. Secondly, it is interdisciplinary; and, finally, it crosses the borders of industries. I will first deal with the scientific nature of nanotechnology.

6.2.1. The Scientific Nature of Nanotechnology

The scientific character of nanotechnology has a number of implications for the application of patent law. Nanotechnology shares some of these implications with biotechnology that was, and is, also very much science based. The reasoning runs as follows: universities are relatively over represented amongst patentees; what is patented is closely connected to results stemming from fundamental research; the patents that ensue have such research have the serious potential to block further research in the field. Yet, the transfer of such fundamental into marketable products often still requires non-obvious steps as the patentability of inventions can only be adequately ascertained by those who are strongly acquainted with the academic literature in the field of nanotechnology. I will elaborate on these implications.

Nanotechnology is still very much the subject of fundamental research, much of which is performed by universities and research-institutes. In Europe, two-thirds of research into nanotechnology is publicly funded, compared to only 45% in the US (Hullmann, 2006: 15), where private investment is much more prevalent. Nonetheless, public investment in nanotech is still significant in both the US and Europe. Universities appear to be particularly avid patentees. They are also in a relatively strong position when negotiating licenses in their patent portfolio: since they are not in the business of manufacturing goods, they seldom need to obtain licenses from other patentees. This makes them much less vulnerable to accusations of patent infringement and that in turn gives them leeway when negotiating the conditions for licenses in their own patent portfolio (Lemley, 2008). In reality, things are of course somewhat more complicated than described here (Shrestha, 2010; Zvoko, 2006). Universities may feel that it is their moral duty to make sure that their research results find wide application in society and this may permeate their licensing policies. Universities may also be dependent upon commercial companies for other than patent reasons. They will want to maintain good relations with commercial companies for purposes such as contract research and access to expensive equipment. This may allow

for a more balanced situation in negotiation room. Nevertheless, there will be great differences between the licensing policies of universities, and universities may treat companies differently on the basis of their ties. These multifaceted situations will translate into a wide variety of constellations for license negotiations. The basic point nonetheless remains that licenses on patents held by universities may not always be as easy to obtain as those held by profit-making entities.

Since research in the field of nanotechnology is to a large extent performed by universities, much of it is of a fundamental nature. Universities develop basic ideas, substances, and processes. In the development of biotechnology, upstream research results, such as DNA sequences, were patented while far removed from a product or service that could readily be offered on the market (Rai, 1999a; 1999b). Such patents frequently act to hinder further research (Kane, 2006) and work simply to reserve a certain research field for a patentee. According to US patent law expert Lemley, it is likely that similar risks are present in the field of nanotechnology (Lemley, 2005). In other technical fields, such as computers, software, the internet, and – surprisingly – biotechnology, Lemley observes that patenting started only after development of the technology was in full swing. In nanotechnology, patents were granted immediately from the outset of scientific development. As a consequence, patents on the basic ideas of nanotechnology – the building blocks of the technology – are much more prevalent. This is likely to burden downstream innovators as it is practically impossible to invent around the basic ideas and elements of a discipline where licenses are not forthcoming.

It is hard to assess exactly the extent to which the problem as described above materialises in nanotechnology. Such assessment is further hampered by the fact that nanotechnology is not one homogeneous technology but rather a collection of different sciences and technologies that have in common the size of operation. The situation of the various nanomaterial platforms – basic molecules – can be very different. Examples of nanomaterial platforms are, *inter alia*, carbon nanotubes (hereinafter: CNTs), buckyballs or fullerenes, and quantum dots. From platform to platform, there are differences between the density of the patent landscape and the degree in which patents are entangled. This becomes all too evident when comparing the patent landscapes for buckyballs and carbon nanotubes. There are no broad patents claiming buckyballs *per se* (Lemley, 2005: 614). A reason may be that buckyballs spontaneously occur in nature (Gerhardt et. al., 1987) and therefore may be unpatentable discoveries. At the same time, carbon nanotubes are claimed in a number of patents. Three patents are often mentioned because of their broad scope: US5747161, a patent of NEC; US5424054, a patent of IBM, and

US6683783, a patent of Carbon Nanotechnologies (Lemley, 2005 and Harris & Bawa, 2007). A fourth patent should be mentioned in this respect as well: US4663230, a patent of Hyperion. The latter patent concerns a composition of matter using carbon nanotubes. Its first claim reads:

> An essentially cylindrical discrete carbon fibril characterized by a substantially constant diameter between about 3.5 and about 70 nanometers, length greater than about 102 times the diameter, an outer region of multiple essentially continuous layers of ordered carbon atoms and a distinct inner core region, each of the layers and core disposed substantially concentrically about the cylindrical axis of the fibril.

This is a broad claim and applications using carbon nanotubes will need to be careful to ensure that they do not infringe this patent. A patent application for the invention has also been filed in Europe (EP0205556). The European patent's first claim is however narrowed down by the inclusion of an extra qualification: 'said fibril is substantially free from pyrolytically deposited thermal carbon'. In Europe, a purer form is claimed but it nonetheless remains a rather broad patent. In conclusion, when considering carbon nanotubes and buckyballs as building blocks, it appears that the former are the object of broad patent claims, whereas the latter are not, or at least much less so.

It could be asked whether these differences have predictive value for the level of innovation. Starting from traditional concerns about the effects of patents on building blocks, one would expect that innovation in carbon nanotubes would suffer. However the opposite seems to be the case. When looking at the number of patent applications, it appears that there are five times as many applications for CNTs than there are for buckyballs (Michalitsch et. al., 2008: 86). The buckyball patent landscape also shows many abandoned patents (Lux Research, 2005). These patent based indications are in accordance with the trend signalled in literature: expectations for carbon nanotubes are high (Harris & Bawa, 2007), whereas Buckyballs have disappointed in not living up to the high expectations placed upon them when they were first discovered (Michalitsch et. al., 2008: 86, Ball, 2005).

So, perhaps the potential for technical and commercial success is a more important indicator for innovation than the existence of patents on building blocks. This does not however indicate the contrary: innovation might still have been more extensive had building block-type patents not have existed in the first place. Building block patents may, for example, create uncertainty as it may well be unclear to innovators whether their activities are covered by the patents and, if so, it may be unclear whether the patents are valid. Uncertainty can act as a strong

disincentive to innovation. Concerns about patents on building blocks can therefore not easily be discarded.

As suggested in the introduction, it is expected that nanotechnology will ultimately lead to concrete products and services that meet the great expectations of benefits. Yet, it has hitherto proven difficult to translate theoretical results into marketable products. Only a few products have appeared on the market. In this respect, Europe lags behind the US (European Commission, 2004: 7). This may indicate that patents are being granted on inventions that have no or at least a very thin industrial applicability. This reinforces the fear expressed above that patents are being granted on basic ideas in nanotechnology.

According to research by Meyer, nano-patents tend to cite only other patents and to a much smaller degree scientific research papers (Meyer, 2001: 298). This is remarkable in view of the fact that nanotechnology is very much a science based discipline. This raises the question as to whether relevant prior art escapes the patent examiners' attention. If this is the case, patents are being granted on inventions that are not novel or that lack inventiveness.

6.2.2. The Interdisciplinary and Cross-industry Character of Nanotechnology

It was suggested above that the scientific character of nanotechnology sits uneasily within the patent system. This section investigates how the patent system relates to the interdisciplinary and cross-industry character of nanotechnology. The former will be dealt with first. The manipulation of matter on the nanometer level is not the prerogative of one single technological discipline. Nanotechnology is thoroughly interdisciplinary, involving *inter alia* chemistry, physics, biology and electronics – and its applications are often the result of a convergence of pre-existing technologies. This interdisciplinary character poses serious challenges to patent examiners; it may entail, for example, that nanotech patent applications sometimes end up with examiners having expertise X while other similar applications end up with examiners having expertise Y. The divisions between examiners with different expertises holds a certain risk for overlooking prior art.[1] Moreover, the lack of a uniform terminology in nanotechnology may magnify the risk of prior art remaining undetected. Yet biotechnology has not, or at least to a much lesser extent, been burdened by these problems; and such a theoretical risk in the area of nanotechnology does not amount to empirical evidence supporting a claim of over-patenting. Empirical evidence is sparse (Featherstone and Specht, 2004). The EPO and the Organisation on Economic Co-operation and Development (hereinafter

[1] The EPO has taken measures to prevent this from happening.

'OECD') are working on monitoring instruments for nanotechnology patents (Hullmann & Frycek, 2007a: 11-12), and these may begin to enlighten us on the empirical practice of patenting in the field of nanotechnology. But even in the absence of empirical evidence, the theoretical reflections about the interdisciplinary character of nanotechnology point to deficiencies that may need to be addressed.

In addition to crossing the boundaries of scientific disciplines, nanotechnology also crosses the boundaries of industries. The cross industry character is mainly important for the manufacturing stage of nanotechnology, but it may expose innovators to a greater risk of accusations of patent infringement (Khanijou, 2007). On the one hand, this is due to the involvement of patentees from other industrial sectors, who may feel less inhibited about enforcing their patents against innovators outside their own industrial sector; on the other, this problem is exacerbated by the added complexity of compliance checking. A company becoming active in the field of nanotechnology cannot limit its compliance checks to the industrial sector in which it is active. It will need to check patents in other industries as well since these patents may impinge upon its activities. As such, such a company may need to actively check patents across a while range of diverse disciplines. Given the size of patent databases, the search for relevant patents may amount to a gigantic task. In this respect, the patent landscape of nanotechnology is more complex than is the case with biotechnology, where all relevant prior art can be found in just one industry or discipline. In view of the fact that most nanotechnology products and services have not yet reached the market and relatively little money is currently being made with nanotechnology, the extent of the problem may not yet be visible in its entirety.

6.3. Addressing the Friction between Nanotechnology and the Patent System

We have seen above that there are multiple reasons that may prevent nanotechnology from reaching its full potential stemming from a potential mismatch between nanotechnology and the patent system. Hereinafter, a number of avenues are investigated for redressing this situation.

6.3.1. Person Skilled in the Art

In patent law, a fictional person skilled in the art is used as a criterion figure. For example, when assessing the inventiveness of an invention an important question is to whom the invention needs to be inventive. Technical teachings that a layman finds inventive may be considered obvious by an expert in the field. Patent law solves the issue by

requiring that an invention is inventive from the perspective of a person skilled in the art. This person skilled in the art is usually defined as a person working in the technological field in which the invention falls and s/he is considered to have average knowledge and abilities. By choosing the person skilled in the art as a criterion figure, the patentability requirement of inventiveness is made more objective. Apart from the requirement of inventiveness, there are other requirements that a patent application must meet and for which the criterion figure is relevant. An invention must, for example, also be sufficiently disclosed in the patent. This means that it must be possible to rework the invention based on the information provided in the patent. Here again, the question can be asked who should be able to rework the invention. Here too, the issue is resolved by choosing the person skilled in the art as the standard by which to measure whether the requirement has been met.

The definition of the person skilled in the art is highly relevant for the determination of novelty, inventive step and sufficiency of disclosure in nanotechnology. If the person skilled in the art is taken to be highly qualified, it is more difficult to meet the inventive step requirement but the disclosure of the invention can be somewhat less encompassing. The person skilled in the art can be assumed to be more adept in applying the technical teaching of the patent. The opposite also holds: defining the person skilled in the art as less highly qualified makes it easier to meet the inventive step hurdle but makes necessary a more encompassing disclosure. In a new field such as nanotechnology, it is unclear how the person skilled in the art of nanotechnology is to be defined.

For example, the interdisciplinary character of nanotechnology has a bearing on the definition of person skilled in the art of nanotechnology. The interdisciplinary character entails that they should be a master of many disciplines. But this leaves open the subsequent question of which disciplines s/he must necessarily master. The function of the concept points the way: with the help of the fictitious person skilled in the art, it must be possible to determine what activity would be considered normal progress in the art and what would be considered to be a major step in the pertinent technology. So, the person skilled in art should reflect the realities in the relevant industry, in this case, the pertinent branch in the nanotech industry. This indeed means that multidisciplinary talents must be attributed to the person skilled in the art. Apart from the abstract question of how to define the person skilled in the art, there is the practical issue that the concrete capabilities of patent examiners may rub off on their perception of the person skilled in the art. In other words, the monodisciplinary restrictions in the capabilities of examiners may influence their perception of the person

skilled in the art. Thus, a tendency towards a low standard may result of innovativeness where even the level of qualification attributed to the person skilled in the art may be different between patent examiners. An examiner may be more inclined to view aspects of an invention as inventive if they are in technology domains with which s/he is less familiar. Being less adept in reading a patent in such technology domains may prompt an examiner to also require a further elaborated disclosure. Whilst it is true that it is not the patent examiner but the courts that have the final say on what constitutes a man skilled in the art, however the determinations of a patent examiner are highly relevant since most patents are never litigated. Nanotechnology litigation is still sparse compared to litigation in other domains. It will probably increase when products incorporating nanotechnology are placed on the market on a large scale. Where patents are litigated, the patent examiner sets the scene for the judgements of the court. For the time being, in any case, there may be variation in the actual standards used in nanotechnology patenting.

Patent applicants may try to use the interdisciplinary character of nanotechnology to their own advantage by engaging in what can be called 'technology shopping'. A nanotech patent may, for instance, concern biological switch. The invention could be dealt with as an electronics invention but alternatively as a biotechnological invention. By adequately formulating the claims in terms of a certain 'participating' discipline, the would-be patentee may try to steer the patent examiner away from relevant prior art. In the same way, it may also be possible to select the standards applicable to the determination of the person skilled in the art, and in its wake, novelty, inventive step or sufficiency of disclosure, since those differ to a larger or smaller extent between disciplines. For inventions in the field of biotechnology, research is usually done by postdoctoral researchers, whereas in most other disciplines the person skilled in the art is a technician of average capability. The person skilled in biotechnology is thus more highly qualified than in most other arts (Hacon & Pagenberg, 2008: 51).

At the same time, biotechnology is apparently qualified as more uncertain science in which a person skilled in the art cannot as easily as in other sciences assume the presence of fixed patterns. This reflects on the definition of the person skilled in the art. The Technical Board of Appeal has defined the person skilled in the art of biotechnology as follows (T 0387/94, Max-Planck-Gesellschaft/Monsanto):

> 'His/Her attitude is considered to be conservative. "He/She would never go against an established prejudice, nor try to enter unpredictable areas nor take uncalculable risks".'

If an invention lends itself to a choice of art, a patent attorney may be able to select a favourable base discipline. By framing the invention in a suitable way, it may thus be possible to choose the standard applicable to one's invention.

A team approach to a person skilled in the art may solve some of the inherent problems associated with the interdisciplinary nature of nanotech inventions. However, the manner of developing a team approach would produce different effects. One of the implementation decisions to be made involves the level of qualification of the team skilled in the art, which of course may vary. If the imaginary team is to be very well qualified, this may raise the bar of inventiveness for nanotech inventions and may make the disclosures difficult to comprehend for any individual trying to make sense of a nanotechnology patent. After all, the drafter of the patent (probably a real-life team) may presuppose all the knowledge available in the imaginary team. It may be contended that this is of limited relevance because any actor involved in nanotechnology works within a multidisciplinary team. However, with a view to openness and accountability to the 'outside world', a lower standard of readability of patents is desirable. This being the case, I would suggest that the imaginary individual partaking in the team should be envisaged as being somewhat less qualified than the person skilled in the art relevant for monodisciplinary inventions. This will force somewhat more elaborate disclosures in interdisciplinary inventions.

Another way to achieve more comprehensible disclosures would be to decouple the inventiveness-person-skilled-in-the-art from the sufficient-disclosure-person-skilled-in-the-art. This would be a more principled intervention in patent law that would require further research, although for the time being at least, nanotechnology does not necessitate such action.[2]

Defining the person skilled in the art as a team and backing this up by creating real life interdisciplinary teams would go quite some way to resolving the problem of technology shopping. A team of examiners is harder to fool than an individual examiner. At the same time, of course, a multidisciplinary team of examiners does not solve all the problems. For example, it is still unclear how to determine the default discipline of an invention, or, in other words, what standards to use when examining nanotech patents.

6.3.2. Novelty and Inventive Step

Nanotechnology is a new technological field and there is therefore relatively little prior art and even less prior art explicitly relating to

[2] See T 60/89, OJ 1992, 268, T 694/92, T 187/93 and T 412/93.

nanotechnology (Zekos, 2006b: 366). A small reservoir of prior art may have the effect of lowering the actual novelty threshold because novelty is easy to establish. This may give rise to broad patents because the formulation of claims does not have to steer around existing prior art. Concerns surrounding the broadness of nanotechnology patents gain extra weight in view of the fact that nanotechnology is in its formative stages of development. The progress currently being made is likely to yield building blocks on which many later applications will be based. While the width of patents now granted may adversely affect follow-on innovators, broad patents may be necessary in order to allow for the large investment needed for developing laboratory findings into marketable products to be recouped (Lemley, 2005: 628-629). Whether broad patents in nanotechnology are at the moment a good or a bad thing is open to discussion. Nevertheless, there can be little discussion that over-broad patents that should not have been granted in the first place must be avoided. An adequate determination of the state-of-the-art is central to the quality of patents. Although it is the patent applicant that must indicate what the nearest state-of-the-art is, it is up to the patent office to detect any deficiencies. This may be an extra heavy burden in the case of nanotechnology, since it is an emergent technology and patent offices struggle to find qualified examiners. The workload of the present examiners is already very high (Barraclough, 2007; Krempl, 2006). In order to ease their workload, patent offices could invest in qualified examiners and in optimising the availability of prior art information, such as technical information in academic journals and other non-patent information. Another avenue through which progress could be made is by working on a standard terminology and metrology in nanotechnology. This is of course not the task of patent offices but that of standard setting organisations, such as ISO and ASTM International.

Early standards on nanotech terminology have already been adopted (ISO, 2008; ASTM Int'l, 2006) or are in the process of being developed (ASTM Int'l, 2009). ISO standard TS 27687:2008 on terminology and definitions for nano-objects was adopted in 2005 and is the first in a planned series of ISO standards covering terminology and definitions for various aspects of nanotechnology. In 2007, the OECD set up a Working Party on Nanotechnology. The remit of the group explicitly addresses the issue of standardisation in nanotechnology (OECD, 2008). However, the work of standard setting organisations often progresses slowly. A technology may not be developed enough to know what standards concerning semantics, measurement and testing are needed. This seems to be the case with respect to nanotechnology. Terminology in nanotechnology literature is extremely dynamic (Hullmann & Frycek, 2007b: 396). Obviously, it is desirable for patent

offices to work with standards that have been set by standard setting organisations, especially if they are adopted globally, so as to makes communication with patent applicants easier. Internal communication between the various divisions within a patent office would also benefit. Further, a standard terminology would also make it easier to detect prior art in patent databases and other literature sources; and may assist in clarifying ambiguities in patent claims, making the scope of patents clearer, both for patentees and third parties, such as competitors and licensees. Given the interest that standards on terminology and metrology represent for the patent system, it seems to me that an argument could be made for the active participation of patent offices in standard setting procedures. Patent offices play an important role in the patent system as gatekeepers for the patentability of nanotechnology inventions. In fulfilling this role, they are highly dependent on a uniform terminology and metrology in nanotechnology. Differences in terminology and metrology can have far reaching implications – ultimately that patents are granted that should not have been granted in the first place. Patent offices should therefore make sure that their standardisation needs are taken into consideration. Moreover, patent offices are in a unique position to see many applications from various nanotechnology domains and are thus in the position to make an important contribution to the standardisation process. In short, there is good reason to have patent offices participating in standard setting processes concerning terminology and metrology.

6.3.3. Industrial Applicability

In situations of technological change, such as with emerging technologies, there is a certain risk that broad patents are being granted on enabling technologies. This has possibly been the case in biotechnology, where patents have been granted on upstream research results (Heller & Eisenberg, 1998; Zekos, 2006a). Theoretically, the requirement of industrial applicability could be used as a brake on overbroad, upstream research patents that are far removed from a product that could be placed on the market. Given their abstract character, they may have no 'practical' application. In reality, however, the EPO hardly uses the industrial applicability requirement for this purpose (EPO, 2006: 170-171).

In the field of biotechnology, patenting authorities have attempted to use industrial applicability for just that purpose. Article 5(3) of the European Directive on biotechnological inventions 98/44/EC indicates that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. It is not quite clear how this provision must be interpreted. One option is to see it as a

mere repetition of the general patentability requirement of industrial applicability. This interpretation does at first seem less likely since it would be nonsensical: it does not add anything to the normal application of the requirement of industrial applicability. Another interpretation may be that the function of a gene patent should be mentioned in the claims as then the patent only would confer an exclusive right to use the gene for the specified function. The latter interpretation would make for specific law for gene patents. In 2005, the European Commission has evaluated the effect of Article 5(3) of the Directive.[3] The Commission indicated that (European Commission, 2005):

> 'as a specific field of technology becomes mature, the application of the normal patent criteria of novelty, inventive step and industrial applicability means that future patents are necessarily limited in scope because the invention claimed has to be distinguished from the vast array of what is already known in the field[11]. As it is now seventeen years since a Directive was first proposed, it may be questionable whether attempting to further refine the scope of protection of gene sequence patents in the light of divergences between national legislations will have any significant effect on actors in the field.'

The Commission indicates that in a relatively short time, this piece of special legislation – if at least it is to be interpreted as such – has made itself superfluous. Apparently, purpose-bound patents do not give patentees an effective protection. Patents would become too narrow. What implications does this have for the desirability of specific rules for the industrial applicability of nanotechnology patents? It is likely that in the case of nanotechnology patents the issuing of overbroad patents will also be a problem associated with the initial stages of development of the technology. The lack of scientific knowledge and prior art in general makes it difficult to draw a line between broad and overbroad protection. Any attempt at a solution of what seems to be a recurring problem with any new technology will be handicapped by the same lack of scientific insight in the nascent technology and therefore be difficult to implement. The slowly growing scientific insight in the technology points in two directions: on the one hand, it points to a solution later in the technology life cycle when more is known about the technology and its underlying science. On the other hand, it points to more transparency right from the start. Opening up possibilities for revocation of an overbroad patent 'later on' could be an effective intervention. Opposition to the granting of a 'European patent' is however limited to just nine months after it has been awarded. In this

[3] See Article 16b Directive 98/44/EC.

respect, the advent of a centralised European court system would bring relief. The development of the legal foundations for a European and Community Patent Court has been set in motion (European Commission, 2009). Lack of industrial applicability can be a ground for invalidating patents later on in a patent's life cycle, especially if no concrete applications of the patented invention appear. It may however not always be easy to determine whether that is the case. For instance, where patented upstream research results can function as research tools, they still may be said to amount to practical applications. This is an argument often raised in biotechnology cases. Furthermore, invalidating a patent later in its lifecycle runs the risk of lessening legal certainty with respect to the validity of granted patents and must therefore be used with care. The other option – working on transparency – may therefore be more fruitful. As indicated above, ensuring that nanotech patents are sufficiently disclosed is important. It is something the courts and the patent office can work towards, even without special regulation (Burk & Lemley, 2003). A change in the definition of the person skilled in the art can lead to more encompassing disclosure. Further, a change in the standard of industrial application – as used by the courts - may result in more exacting indications of the industrial application of the invention in the patent.

6.4. Conclusion

According to the European Commission, Europe is not good at transforming nanotechnology research into marketable applications (European Commission, 2004: 7). Thus, while the numbers show that nanotechnology based patents have not reached the high volumes some would have hoped for, patent law is not to blame (Kinsler, 2006). The patent system offers enough room to patent nanotechnological inventions. The possibilities for patenting nanotech inventions should therefore be considered positive.

At the same time, nanotechnology has a number of characteristics that raise the risk of over-patenting, such as patents on building blocks of the technology and overlapping patents through inconsistent use of terminology. This chapter has argued that such concerns need to be addressed. A number of avenues have been identified for improving the application of patent law, specifically as it relates to the inherent characteristics of nanotechnology inventions. For instance, the standard of a person skilled in the art of nanotechnology should be set at the level of a team of not too highly qualified researchers in the relevant technologies so that disclosures of inventions become more exacting. Furthermore, patent offices should closely follow the work

being done towards the standardisation of terminology and metrology in nanotechnology, and, if possible, they should participate in standard setting processes in order to lessen ambiguities that complicate the process of patenting. This alone would result in a much higher level of quality of granted patents. At a later stage, when applications of nanotechnology are being developed and appear on the market, ways of facilitating the licensing of nanotechnology will also become a relevant instrument for dealing with innovation in the field of nanotechnology. But that is a future concern...

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Chapter 7. A 'Scanning Probe Agency' as an Institution of Permanent Vigilance

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Abstract
When it comes to calling for the regulation of nanotechnology, expectations of regulatory tools that offer assurance that all marketed products are safe will be disappointed. In the face of non-knowledge, classical regulation, but also voluntary schemes of soft law, fail to do justice to the heterogeneity of all the various technologies, processes, or products that are labeled 'nanotechnology'. This paper will provide an overview of the basic structure and operating procedures of a proposed model institution called Scanning Probe Agency, that would be charged with rendering desired scientific developments compatible with social well-being, while maintaining a commitment to the principles of classical regulation such as public oversight, political transparency and the possibility of participation.

7.1. Introduction

Research regarding the safety of nanotechnology has to contend with profound gaps in knowledge regarding the toxicity of nanomaterials. Its provisional aim, therefore, is to structure the field in a rather elementary way, including attempting to develop test procedures, standards and norms. A formally instituted means of regulation, such as setting legal thresholds, appears unachievable for systematic reasons (cf. Führ et al., 2006). However, the sustained focus on the toxicity of nanomaterials fails to do justice to the complexity and multiplicity of nanotechnologies and the associated demand for a comprehensive approach to ensure that nanotechnological developments are compatible with human, environmental and social health.

In this paper we want to outline[1] an institutional model that meets the safety and security demands of human health, the environment and society – an institutional model (we provisionally call Scanning Probe Agency) that conducts a reflexive adjudication process. It employs the methods of document analysis, expert interviews and a workshop with

[1] In a project carried out for the German Federal Ministry for Education and Research the nano-office at TU Darmstadt presented a report (Lösch et al., 2008) consisting of an overview and an analysis of existing regulatory and soft regulatory efforts concerning nanotechnologies (both national and international). Further, the report proposed the creation of an institution for the regulation of nanotechological developments.

invited experts. Philosophical and sociological considerations of the problems of non-knowledge, transparency, responsibility and social robustness are the starting point and the frame in which the deliberations are embedded.

The results include the following points. The place of classical regulation has been taken by precautionary measures such as observatories, voluntary codes of conduct and stakeholder dialogues. By themselves, these cannot meet the challenges posed by nanotechnologies, nor do they satisfy the need for regulation. These soft measures of an expanded notion of regulation and precaution do not provide what classical regulation has to offer, namely public oversight, political transparency and legal certainty – guaranteed by a publicly accountable institution. A generalized precautionary approach thus also signifies a surrender of the political option of intervention. However, the option of influencing processes of innovation is indispensable for responsible, circumspect and socially robust action with regard to the uncertainties associated with emerging nanotechnologies.

These considerations call for a reflexive adjudication procedure as a collective learning process and as a means of earning public trust. This reflexive adjudication consists in an evaluation and contextualization of existing regulatory approaches that is politically transparent and open to public scrutiny. The way in which existing institutions and regulatory procedures deal with nanotechnologies is judged as more or less adequate with regard to public demands for knowledge, communication and effective action. A 'scanning probe agency' (SPA) is recommended as a suitable institution to organize such procedures of reflexive adjudication. It should be established under the auspices of a nationally and internationally respected academy of science.

7.2. Nanotechnology and Existing Regulation

'Nanotechnology' is an extremely multifaceted and complex phenomenon. Both the amorphous boundaries of 'nanotechnology' as an entity and the correspondingly varied safety requirements of products and production processes make it virtually impossible to adapt existing regulatory mechanisms such as REACH, although REACH is seen by some as the first step towards a 'hybrid governance' (cf. Hey et al., 2007).[2] The limits to and gaps in knowledge are plentiful

[2] Hey et al. (2007) conclude that REACH (reform of chemicals policies) is not so much an example of bureaucratic regulation: A "closer look shows that there are many new forms of governance in REACH. This mixture or old and new may open a more realistic and promising perspective on the reform of European policy-making."

– including a lack of standards, characterization and testing procedures etc. – and pose a special challenge to safety research and regulatory measures (cf. Krug and Wörle-Knirsch, 2007). Attempts exist to make up for the systematic deficiencies in the legal regulatory system by means of 'soft' measures, such as continual observation of developments, industry self-regulation via codes of conduct, and multi-stakeholder dialogues intended to establish legitimation (cf. Lahl, 2006; Nentwich, 2007; Wilson, 2006; Schomberg, 2006). However, such measures – guided as they are by a vague notion of precaution – are not capable on their own of meeting the challenges posed by 'nanotechnology' in any appropriate way. They are an attempt to transform ignorance into a kind of certainty. The phenomenon of 'nanotechnology' also confronts us with systematic limits to knowledge (cf. Dupuy, 2004; Böschen and Wehling, 2004; Nowotny et al., 2001) that cannot be overcome in a preventative manner. Many of the opportunities and risks associated with nanotechnologies will become manifest and quantifiable only in retrospect – in the course of product use.

The 'soft' measures associated with an 'extended' concept of regulation represent a departure from the principles of classical legal regulation. The latter include public oversight, political transparency and legal certainty and are guaranteed by a publicly accountable and responsive institution, permitting effective intervention. The 'soft' measures alluded to above, however, constitute a retreat from these principles, whereas the option of intervening in, and influencing innovation processes is indispensable for dealing in a responsible and socially robust way with the uncertainties encountered in this new field of technology.

Given these considerations, a reflexive adjudication procedure seems both necessary and appropriate as a collective learning process and a means of generating public trust. This procedure would provide a means of contextualizing and assessing regulatory practice in a way that is both open to public scrutiny and politically transparent; its focus would be on what is required in terms of knowledge, communication and action, as well as on the scope and suitability of measures taken thus far in the context of an 'extended' concept of regulation. The outcomes of observations from the special observatories, 'code of good practice' procedures and stakeholder dialogues would all be integrated into such a reflexive adjudication procedure. Its guiding question would be: 'Is nanotechnology in good hands?'

In short, the need for an SPA arises from the following diagnosis of relevant problems:

- The term 'nanotechnology' is used to refer to a large number of products – cosmetics, antibacterial surfaces, sensors, nano-

semiconductors, food additives, as well as misleadingly termed 'nano-products'. 'Nanotechnology' (in the singular) does not refer to a particular technology, but is a term that absorbs a whole range of societal visions regarding new technologies – as such, it is a communication phenomenon or discursive artefact. A reflexive adjudication procedure is therefore required that deals with everything that gets referred to as 'nanotechnology' and that requires differing forms of official authorization, observation or monitoring.

- Reliable product safety can not be guaranteed solely through the use of standardized and tested component materials (e.g., nanoparticles), given that small production-related deviations at various stages of the manufacturing process in themselves can introduce new uncertainties. The levels of fault tolerance established for products and their use can represent a spectrum of potential risks that can only be judged by *means of greater vigilance* applied throughout the life cycle of a product (cf. Pfautsch, 2007; Führ et al., 2006; Nordmann, 2010). A reflexive adjudication must make this circumstance publicly transparent.
- Problems that arise in relation to a specific product labeled as 'nanotechnology' may have an impact on the way society perceives 'nanotechnology' as a whole and everything associated with it. This is why an assessment open to public scrutiny is required that 'disentangles' the different dimensions of selected products and simultaneously takes into account the way they are linked to the overall phenomenon.
- Since consumers encounter 'nanotechnology' only in product-integrated form, uncertainties arise in a variety of areas – e.g., the interaction between different kinds of nanomaterials and solid bodies in the product concerned, interaction with the product environment, variations in individual usage. Only a reflexive adjudication procedure is capable of learning from a synoptic presentation of all the various required forms of knowledge – from scientific knowledge to the knowledge implicit in user habits and knowledge of relevant ethical dimensions. This can form the basis for a socially robust adjudication in each instance.
- The perspectives from which a nanotechnological product is viewed – for instance, chemical-toxicological, materials science, epidemiological or occupational health views – influence perceptions of potential regulatory requirements. What is needed here is a reflexive mediation between various forms of expertise and regulatory responsibility. The generous promises and expectations associated with 'nanotechnology' by its visionary advocates prompt a corresponding demand on the part of society

for an integrated examination of nanotechnology's compatibility with human, environmental and social well-being.

7.3. Outline of a Model Institution

The scanning probe agency (SPA) is conceived as a learning community consisting of experts from all the relevant spheres of society – academia, industry, the unions, churches, NGOs and consumers, and so forth. The task of this community is to formulate judgments on selected nanotechnological products, processes and discursive phenomena and to present these judgments in public, while also giving a clear indication of where the limits to existing knowledge lie. This form of adjudication – one open to public scrutiny – is designed to render desired nanotechnological innovation processes compatible with social well-being while maintaining a commitment to the principles of classical regulation, such as public oversight, political transparency, and the possibility of intervention. This would be guaranteed by the framework provided by a publicly accountable and responsive institution that enjoys broad social acceptance. The latter would elaborate recommendations that have undergone a process of social negotiation. Such recommendations might include, say, research support for desired innovations, or regulatory precautionary measures in the case of products deemed to give cause for concern.

7.3.1. Three Basic Functions

The SPA is characterized by three basic functions:

- a *scanning* function for broadly surveying the field of scientific-technical developments and identifying those innovations, products and discourses that require clarification;
- a *probing* function for selecting specific issues and conducting communication about their various dimensions within a 'learning community of experts'; sample probings will be conducted by means of testimonial hearings (involving witnesses from research, official authorities, industry, etc.);
- an *agency* function for conducting public, court-like adjudication procedures, for intervening in debates and for devising socially robust recommendations that specify, for example, the need for action on the part of other regulatory authorities as well as deficiencies in research and communication.

The three functions can be summed up in terms of surveying the terrain, conducting hearings on selected issues and elaborating recommendations in a collective and publicly transparent manner. The problem in question is thereby placed within an overall context of the health-related, environmental and social implications of

nanotechnologies. These are the functions that mark out the SPA's reflexive adjudication procedure from the models of observation, self-regulation and public engagement that are inappropriate, inadequate, or simply too weak for 'nanotechnology'.

The SPA itself fulfils no regulatory functions and conducts no research of its own; its aim instead is to derive new insights on the basis of selected case studies. Because of this, it is able to function with a slimmed-down level of staffing: a small full-time service team and a learning community in the form of a panel of honorary experts. Given the demands posed by integrating the required forms of expertise in a suitable way – using the format of the 'learning community' – and by adjudication procedures open to public scrutiny, it appears most appropriate to affiliate the SPA with a scientific academy of both national and international renown, ideally (in the case of Germany), for instance, the new German National Academy of Sciences. The integration of expertise and the intended effectiveness of its recommendations demand that the SPA be situated within a national and international network consisting of institutions and organisations that possess the knowledge needed for the learning process and from which experts can be recruited for the adjudication process. The way the model institution is conceived in this paper, is operating on a national level, while it also could be adapted to work on an international level.

7.3.2. Two Modes of Working

In practice, SPA is distinguished by two modes of working:

1. a normal case mode in which learning processes and public adjudication procedures (including recommendations) are initiated and conducted – either in response to requests coming from society or according to the interests expressed by the participating experts – in relation to selected nanotechnological innovations, products or discursive phenomena (the period for working on a particular issue is about 12 months);
2. an incident mode in which the SPA is able to respond in a flexible and *ad hoc* manner to unforeseen externalities – such as controversial products, scientific disagreements or political protests. Here, the SPA assesses, for example, the effectiveness and appropriateness of measures implemented by the regulating authorities in cases of crisis (e.g., removing a harmful product from the market in response to cases of illness) and elaborates recommendations aimed at improving measures that might be taken in similar cases (the period for working on a particular issue is approximately 2 months).

7.3.3. The Point of Reference

The SPA model is intended as a response to the Zukunftsforum Nanotechnologie ('Nanotechnology Forum for the Future') envisaged by the German Federal government for considered, interdisciplinary dialogue, and sees itself as a contribution towards identifying appropriate funding initiatives. The establishment of an SPA would create an official institution in the position of mediator that is both responsive to public concerns and politically transparent, and which, by means of its reflexive adjudication procedure, would be able to provide ongoing support for and critical assessment of, among others, the projects that are part of the Nano-Initiative-Aktionsplan 2010, such as the Nano-Dialog initiated by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Ministry of Education and Research (BMBF) project NanoCare, the working groups of the Federal Ministry of Labour and Social Affairs (BMAS), the consumer protection measures instituted by the Federal Institute for Risk Assessment (BfR), as well as the public information activities of BMBF campaigns such as Nanotruck. The findings from these would be integrated into adjudication procedures and recommendations that are open to public scrutiny. This would meet the need for public monitoring and the possibility of intervention in innovations and regulation. Thus the origin and the primary operating level of the SPA model are on the national level. To implement such an institution in other countries, or on an international level, the different structures of the respective regulatory and institutional landscapes would have to be taken into account; the SPA, as it is described in this paper, is conceived as a model that is based upon general regulatory issues and thoughts from the philosophy of technoscience (cf. Nordmann, 2010); the question of a concrete implementation is not covered in this paper.

7.4. Requirements and Objectives of the Model Institution

The large number of systematic limits to knowledge and corresponding wide-ranging demands for safety and security on the part of society pose a challenge to regulatory measures for 'nanotechnology.' These cannot be tackled solely by observatories, codes of conduct, stakeholder dialogues or other measures of an expanded and softened conception of regulation. These are some of the dimensions we have identified with regard to systematic limits of knowledge:

- the multi-layered nature and variability of what is meant by 'nanotechnology' as a socio-communicative phenomenon;
- limits of standardization due to nanoscale sensitivities to even slight variabilities in the context of production;

- the entanglement of societal perceptions of specific cases (e.g., harmful products) with the phenomenon of 'nanotechnology' as a whole;
- limits to knowledge arising from complex interactions as nanotechnological components are integrated into products and products into user environments;
- dependence of regulatory authorities on particular perspectives, such as chemical safety, technical function, industrial standards and norms.

All these dimensions present the legal regulatory authorities with difficulties they can not resolve. In addition, the measures associated with an expanded conception of regulation (observatories, codes of conduct, stakeholder dialogues) are overburdened by such fundamental forms of non-knowledge and systematic limits to knowledge. This is because these measures – guided as they are by a notion of precaution – are grounded in the assumption that knowledge gaps are temporary and merely epistemic, that is, that they can be overcome as science progresses and that positive, quantifiable and therefore certain knowledge will be generated.

The idea of observatories, mechanisms of self-monitoring and dialogue is to institute a form of permanent and ongoing vigilance that buys time for the acquisition of more comprehensive knowledge to which legal regulatory mechanisms can be adapted flexibly (e.g., incrementally as Berger, 2007 and Franco et al., 2007 discuss). The expectation is that this comprehensive knowledge will encompass not only scientific, technical and industrial facts but also economic interests, user behaviour, ethical concerns and so on. Given the existence of systematic limits to knowledge, observatories and the like function as open-ended measures based on permanent vigilance and are aimed at integrating ever new forms of knowledge. On the one hand, these measures continuously produce new knowledge that is able to feed into the actions of regulatory institutions. This knowledge is acquired, for example, in the course of efforts at standardization, through data collection required for the implementation of 'codes of conduct', or as the outcome of conversations between stakeholders in the dialogue processes. On the other hand, however, new gaps in and limits to knowledge also continuously become apparent in these projects, which in turn call into question the producers' claims to safety, security and certainty. This observation is not new and does not apply exclusively to 'nanotechnology'. Nonetheless, in a field of technology that unites so many different production technologies within a single overarching concept, the systematic constraints of knowledge become multiplied (cf. Dupuy, 2004).

If nanotechnologies are to be dealt with in a way that is socially acceptable and, as such, conducive to innovation, it is necessary to integrate the findings of the observatories, codes of conduct and stakeholder dialogues in the form of a collective, public and transparent adjudication procedure based on selected cases. The objective is to elaborate socially robust recommendations for regulation, research and communication by identifying what is required in terms of knowledge, communication and action. These requirements can be fulfilled only by a visible authority responsive to public concerns that brings together the necessary areas of expertise, suitable forms of reflexive-learning dialogue, political transparency, public assessment and effective intervention in a single institution.

For this purpose, we propose the establishment of a Scanning Probe Agency (SPA). This model consists of a learning community made up of experts from a diverse array of social spheres (including science, industry, unions, churches, NGOs and consumers). The experts have to be chosen (and invited) on the basis of their expertise and their reputation by an independent board. The objective of this community is to reach judgments about selected nanotechnology products, processes or discursive phenomena and, in doing so, to lay bare the criteria and difficulties associated with the formation of such judgments. This process of public deliberation can orient nanotechnological innovation processes towards conditions of societal acceptability and social well-being. The measures associated with 'expanded regulation' will be integrated into the reflexive adjudication procedure. They benefit from the procedure by being tied back into a stronger regulatory concept that holds onto the ideals of classical regulation, despite the deficiencies of legal regulatory mechanisms.

It has become clear that the SPA is designed to especially meet the regulatory challenges that arise in the context of nanotechnologies, since it has become important to find a middle ground between classical regulation and the various voluntary schemes of soft law. This – in principle – makes it also useful for any other new or emerging technology that (for the same or similar reasons) escapes the traditional categories of regulation.

7.5. Type and Designation

The institution developed here is provisionally described as a 'Scanning Probe Agency'. Whether the choice of name is a happy one or not is an open question. That the designation is apt is beyond doubt, though – not least because it refers to an instrument that embodies nanotechnology as no other does, namely the scanning probe microscope, which not only observes but actively intervenes in the

nanoworld. However, the designation is especially apt because it names the three basic functions of the model (see Figure 7.1 below):

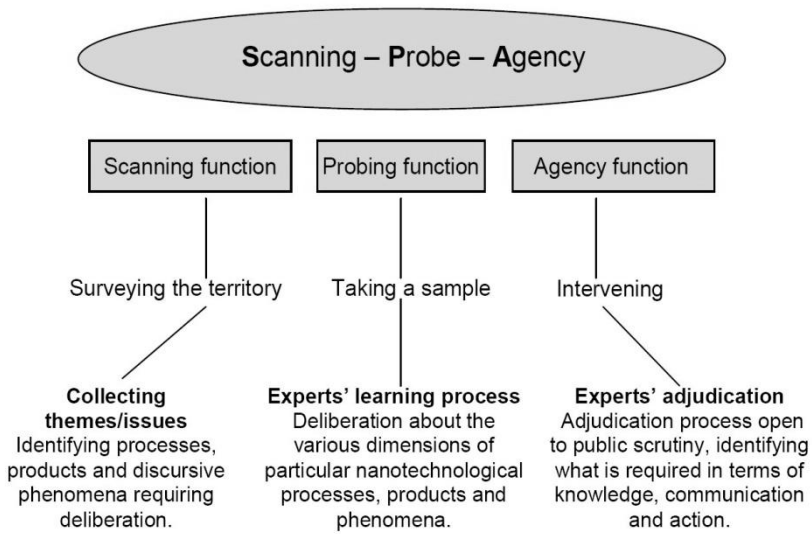

Figure 7.1. The three basic functions of the Scanning Probe Agency

7.6. Functions of the SPA

In its scanning function, the SPA surveys the current nanotechnological landscape. This includes research trends, the marketing of new nanotechnology products and the state of debate within society as well as within the social and human sciences on the subject of 'nanotechnology'. In carrying out this task, the SPA makes use of the data and findings that originate within scientific specialties, or are collected by observatories or generated in the course of implementing codes of conduct (e.g., regarding the opportunities and risks associated with particular production processes). Its synoptic view of the field of 'nanotechnology' also includes media research and the reports emerging from dialogue processes. One aim of this scanning exercise is to reveal emerging issues and trends, characteristic or problematic case studies or potential problem zones. These might then deserve a closer look that can offer new insights or suggest novel ways of dealing appropriately with certain issues. The scanning function can also serve to identify patterns in seemingly disparate events and to

establish connections in order to trace latent developments and create the necessary level of vigilance in a timely fashion.

The aim of the SPA's scanning activities, therefore, is not to create a complete and systematic collection of the widest range of knowledge possible, but rather to provide an overall picture of trends that require clarification and are significant in relation to different areas of society – such as the representation of nanotechnology in the media, demands for regulation by policy makers, risk analysis and safety research, product management and consumer protection, and concerns raised by unions, environmental organisations or churches. There are two complementary ways of carrying out the work of identifying specific cases, problem areas or developmental patterns that require deeper understanding and sustained engagement. One is via the scientific staff of the SPA ('scanners'), and the other consists of issues being brought to the attention of the SPA by way of specific inquiries from social actors – be they members of parliament, ministries or authorities, companies, advocacy groups or individual citizens.

When it then takes a closer look at the issues in question, the work of the SPA shifts to its probing function. Here, the SPA's broadly interdisciplinary expert panel turns to selected case studies and thematic areas for which there is a greater need for clarification and particular demand from within society. The experts form a learning community in which highly diverse forms of knowledge come together, including natural and social-scientific knowledge, knowledge of production processes, knowledge about economic and investment issues, theological and ethical expertise, knowledge about work and safety issues and innovation processes, consumers' knowledge of usage patterns. The learning process is characterized by collective knowledge acquisition in the form of informative exchanges among the members of the group but also in the course of court-like hearings. At these hearings, invited witnesses will be questioned about their experience in research laboratories, consumer protection work, regulatory processes or commercial enterprise and in their involvement in particular situations or events. This collective learning process feeds into the formation of a judgment by the expert panel.

Finally, in its agency function, the expert panel takes its findings into the public sphere and thereby intervenes in ongoing debates. It does so by presenting in a public forum not only the judgment reached by the learning community. It also shares with the public the various considerations and difficulties that were encountered in the course of the adjudication procedure. It will also present a dissenting opinion, should such exist. In this way, the knowledge and the questions that contributed to the deliberation of each specific case are rendered open to scrutiny, and a high degree of transparency is achieved. The

judgment reached in each case may involve recommendations for scientific and social scientific research, policy, regulation and communication strategies. These recommendations from the SPA have no legal or otherwise binding status and do not overlap with the work of agencies that are already implementing existing regulations. As such, the SPA has a clearly delineated area of responsibility that encompasses everything associated with 'nanotechnology'. The SPA has no formal powers, however. Its authority is based on the balanced composition of the panel of experts, on its publicly transparent judgment and its orientation towards relevant questions, and thus its ability to focus on critical concerns regarding opportunities and risks of nanotechnologies. In this respect, the SPA is comparable with the German government's National Ethics Council.

7.7. Operational Modes

7.7.1. Normal Case Mode

The members of the expert panel or the three 'scanners' on the service staff propose themes or issues in relation to which they perceive a need for greater clarity and which they believe are of particular importance to society. These themes may emerge either from their observations of nanotechnological developments and discourses, such as those made at the observatories or at stakeholder dialogues, or from experiences in their own area of work – or simply out of their own personal interests and expertise. These may be practical problems with regard to workers' health and safety, issues to do with the toxicity of certain substances, research programmes and visions, or statements concerning the role of precautionary measures etc. However, queries may also be put forward by parliamentarians, citizens or manufacturers. Where necessary, research on selected issues will be conducted by the service staff. Once these scanning activities are completed, the probers, together with the administrators on the service staff, will prepare the first annual meeting of the expert panel, at which suggested themes will be considered and one of them selected. The informed opinions offered by the members of the expert panel based on their various fields of work, along with their assessments of the importance of the issues in question, play an important role in this decision. The learning process thus begins with judgments regarding the salience of this or that technology trend, ethical concern, regulatory decision, funding initiative or media representation.

Once they have agreed upon the issue to be discussed, the members of the expert panel first exchange information with one another concerning the current state of knowledge, or gaps in knowledge, and current perspectives on the issue. They and the service

staff propose 'witnesses' to be invited to the hearing, e.g., university researchers, representatives from industry, officials at government agencies etc. The hearing takes place in conjunction with a closed expert workshop at which a collective judgment is formulated that is subsequently presented to a larger public. These judgments contain assessments and proposals for research, regulation and communication.

Illustrations of the scope of possible judgments are:

- Assessments of the preparedness of regulatory agencies for dealing with the emerging aspects of particular innovations; judgments about the extent of their capacity to act, including suggestions for improvements in the implementation of regulatory guidelines.
- Recommendations to companies regarding appropriate measures (such as product labelling), in order to satisfy consumers' real informational needs, that is, without producing a surplus of useless information that is available for any nanoproduct.
- Judgments about the extent to which certain promises or fears in an area of nanotechnology are justified or misleading, and establishing accountability for any visionary claims made on behalf of nanotechnology.

The judgments of the expert panel need not involve a consensus. Ideally, they should include a majority and a minority opinion, in order to underscore the force of any particular judgment and to accentuate unresolved differences that are due to gaps in unequivocal evidence. A record of the judgment and the process leading up to it will be prepared by the 'probers' on the service staff and presented in appropriate form for subsequent public debate.

Immediately after the closed expert workshop, its findings, conclusions and the judgment itself will be presented in the context of a public event and opened up for discussion. The public forum, or conference, can be attended free of charge by interested groups. The chairperson of the expert panel will provide an informal account of the workshop and its adjudication process. The individual experts on the panel will present their (various) assessments that led to the judgment (majority and minority opinion). This serves to illustrate the difficulties and learning impacts encountered along the way. In this way they render the adjudication process transparent. They respond to questions and objections by participants in the public forum. This provides a last opportunity for the expert panel to examine its judgment in light of possibly novel considerations that emerged during the public discussion. The judgment is then finalized and made available to the media.

7.7.2. Incident Mode

The aim of the SPA is to facilitate learning processes between different kinds of knowledge and expertise on the expert panel. This should occur not only in relation to the panel's own interests or inquiries from outside; rather, the SPA's reflexive adjudication procedure must also be able to deal in a flexible and *ad hoc* manner with the contingency of unintended and unforeseeable incidents. Cases such as the illnesses brought on by 'MagicNano' (Magic Nano Glass Sealer and Magic Nano Ceramic Sealer in spray doses with a propellant caused respiratory disorders) both constitute an 'incident' and trigger a 'regulatory crisis' among existing regulatory agencies. In such cases, the SPA and the regulatory agencies can learn from each other's responses and recommended measures. However, the way in which an incident is addressed by the SPA is completely different from the way a crisis is managed by a regulatory agency. Measures taken by official authorities to avert danger and measures recommended in the course of the SPA's reflexive adjudication procedure should prove complementary with respect to particular incidents. For example, a case such as 'MagicNano' is a good opportunity for the expert panel to examine subsequently what worked and what did not work as public agencies, the media and society at large dealt with this case.

It is possible to imagine various examples of incidents with which the SPA would concern itself. What they have in common is their ability to cause perplexity among both experts and the broader public, given the way in which fact and fiction are hopelessly entangled in nanotechnological development, as are knowledge and ignorance, issues of safety, security, certainty as well as more general socio-political topics, expectations of nanotechnology and actual experiences with nanotechnological products. Relevant incidents may thus have quite diverse triggers, as demonstrated by the following examples.

Example 1: Harmful Product

In a case such as 'Magic Nano', the harmful product would be the externality that prompts the SPA to initiate its incident case mode. The SPA would analyse and assess the communication difficulties that exist between the various actors involved in the case. The SPA would have to bear in mind, for example, that although 'Magic Nano' is not a product that contains nanoparticles, it still counts as a 'nanoproduct' because 'nanotechnology' is a heterogeneous field of ill-defined product developments that include merely attributed characteristics.

As is well known, 'Magic Nano' contains no nanoparticles, but the thickness of the protective film produced by the cleaning spray lay in the nanometer domain. Clearly even the manufacturers were not aware that there were no nanoparticles in it – an episode that demonstrates

how difficult it is to explore and control the world of nanoparticles and nanoproducts by means of routine technical or legal monitoring.

In such a case, the SPA's adjudication might point out that the responses of agencies and/or industry were highly effective and appropriate, but that a number of crucial questions were not addressed, such as those regarding the lack of transparency in the production and marketing chain – why, for example, was it so difficult for the various actors involved to determine the nanodimensions of the product? How could such a product obtain a 'TÜV' label (confirmation that the product has been officially tested and approved)? Why are there no suitable testing procedures in place for the purpose of awarding such a label?

Example 2: Scientific Controversy

An incident could also be triggered by scientific controversies, contrary expert opinions or scientific promises communicated widely in the media.

It is conceivable, for example, that a new debate about nano-assemblers or irresponsible science could be opened up by a sensational media presentation that presents current research as a preliminary stage towards the creation of self-replicating nano-machines. The SPA's work here would consist in putting one-sided attributions into context, disentangling them and probing them for their serious and substantial content, in order to render visible the genuine problems that are articulated in such visions of out-of-control technology. It might be possible, via a reconstruction of the incident, to identify as the original trigger for such a controversy the propagation of a highly visionary cost-intensive medical procedure that makes use of nanoparticles. Research institutes, industrial companies and the media propagate the promise that this procedure will heal previously incurable diseases. Funding agencies and research policy makers subsequently provide generous grants for basic research on this procedure, even though the scientific methods and technical procedures remain extremely controversial. Scientific journalism then amalgamates the vision of self-replicating nanomachines and the fact of generous public funding, which may then lead to a blanket critique of both nanotechnology and national research policy.

In such cases the adjudication of the SPA could consist in disentangling the scientific, political, economic and other factors involved in the controversy. Also, the SPA's expert panel would judge who – including the scientists and journalists involved – might be held accountable for the statements that encouraged the discourse about the limitless possibilities of nanotechnology. In this instance, the adjudication could also contain recommendations for better ways of

monitoring and communicating the criteria of national research funding.

Example 3: Political Protest

A third trigger for an incident could be a political protest movement. Such a case could be similar to the protest of the Grenoble Opposition to Necrotechnologies (GON, 2006), which justified its demonstrations against the opening of MINATEC in June 2006 by reference to the expansion of a global-capitalist surveillance society. Nanotechnology was equated, for example, with the spread of 'intelligent cameras' throughout society in 'subcutaneous implants' and 'biometric systems', and was described as a 'blitzkrieg against life'.

The aim of an SPA adjudication in such a case would be at once to establish differentiations within 'nanotechnology' and to put the protest into context. For example, it would be necessary to identify where there are genuine data protection concerns arising from the nanotechnological refinement of sensors. It would be necessary to make the point that this innovation represents only a small part of nanotechnologies and that other applications could be more closely aligned with the goals of the protest movement. A differentiation would also need to be made as to whether such a protest should not be addressed elsewhere – not so much to the institution that came up with the scientific-technical innovation as to political institutions which may well define the situation that is the target of the protest. To put it succinctly: the SPA adjudication would have to take the protest itself seriously, in order to determine which of its aspects ought to be taken seriously with regard to 'nanotechnology'. This would enable such protests to be understood rather than simply being dismissed as irrational from the start.

7.8. Conclusion

The three functions of the SPA (scanning, probing, and intervening) come together in the learning impacts that emerge from the reflexive adjudication procedure. They orient the SPA towards the indispensable ideals of public oversight, political transparency and the possibility of intervention by an open and responsive agency that provides the greatest possible legal certainty. In this respect, to institute an independent learning community is also a means of drawing the amorphous, heterogeneous and vision-laden phenomenon of 'nanotechnology' into the sphere of governance and thereby to establish trust among citizens in processes of innovation and in the regulatory regime. The learning impacts are primarily twofold:

1. By encountering the perspectives of their peers in the course of their adjudication procedure, the experts come to know the various assessments, approaches and experiences that exist in the various spheres of society, such as scientific disciplines, industry, governmental agencies, consumer protection, environmental organisations, unions, and churches. This encounter with different forms of knowledge feeds into the joint adjudication process. Thus, the adjudication is not only a matter of assessing scientific-technical background information but also a matter of appreciating its social and cultural significance. Citizens' representatives learn from scientists and engineers, while researchers and developers for their part learn something about society's traditional values and concerns. Accordingly, the reality represented by the adjudication is rendered multidimensional.
2. The openness of the adjudication procedure to public scrutiny renders the individual steps transparent, facilitating understanding and critical assessment. This distinguishes the work of the SPA fundamentally from the mere provision of information by observatories and other measures of expanded regulation. The interface between expert knowledge and public interest should not consist in a database, an information event or an expert report, but rather in a process of adjudication that is rendered transparent. Any interested citizen can find out how difficult it is in a situation of fundamental uncertainty and a proliferation of public statements to find a responsible way of dealing with the opportunities and difficulties that arise in the emerging field of nanotechnology.

These learning impacts can engender public trust, although such trust entails far more than a set of consumer protection measures. Trust includes confidence in political processes and the governability of the emerging technology. This means that the concerns of the general public need to be taken seriously first of all – a fixation on health and environmental risks is not sufficient. Matters of civic concern include more generally the compatibility of a new technology with human health, the environment and social welfare. These are related to issues of justice and solidarity as well as national and international security, but also to a fair and responsible expenditure of state funds. Citizens' concerns should be taken seriously by doing more than merely informing various publics and eliciting their opinions. Beyond this, the SPA invites citizens to participate in the difficult process of adjudicating an issue.

By generating both learning impacts and public trust, the SPA can contribute to a culture of 'risk preparedness'. This consists in the willingness to accept unknowns for the sake of real benefits, and involves a circumspect attitude towards knowledge gaps that cannot be

closed. Without the ability of our societies to distribute the burdens of ignorance and vigilance equally among their citizens, nanotechnological innovation will be unlikely to take root.

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Part 3. The Dimension of Time

Chapter 8. Regulating after Parfit: Welfare, Identity and the UK Embryology Law

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Abstract
The observation that so-called 'genesis questions' – about the creation of lives *ab initio* – raise unique philosophical problems is in danger of becoming trite. In the quarter century since the publication of Derek Parfit's seminal *Reasons and Persons*, much attention has been dedicated to the obligations we might owe to the future people that we choose to create, and about the thorny question of how our choices might impact on the identities of those people. To what extent, though, have these discussions impacted on how artificial reproductive technologies are actually regulated in practice? In the United Kingdom, at least, recent legislative developments give little encouragement that the insights of academic lawyers and ethicists are guiding policy in this area. The Human Fertilisation and Embryology Act 2008 came into effect in autumn 2009. This paper proposes firstly that parts of the Act fail to answer – or even acknowledge – questions of identity and obligations to future contingent people. Secondly, it asks what an approach grounded in a consistent approach to identity questions might look like. As well as the Parfitian 'non-identity' model, I briefly consider some alternative ways of looking at genesis questions. Ultimately, I conclude that, while the Act certainly does not represent a Parfitian approach to such questions, it is not clear that it does justice to these alternatives; indeed, it displays scant awareness of the wide-ranging and rich philosophical debates that have surrounded these questions since before the first attempt to legislate on reproductive choices.

8.1. Introduction

The UK's new Human Fertilisation and Embryology Act received Royal Assent[1] on 13 November 2008, and the majority of its provisions came into effect on 1 October 2009. This long-awaited[2] updating of the rules governing assisted reproduction treatment and embryo research

[1] This is the final stage in the UK's legislative process, after which draft legislation (referred to as Bills) becomes part of the law (referred to as Acts) – although in practice, some time may elapse before an Act takes effect.

[2] The UK Government announced a review of the existing legislation in January 2004. There then followed a lengthy consultation process, at the end of which a Bill was produced, which was in turn the subject of intensive scrutiny and debate in Parliament.

amends and supplements the previous legislation[3], as well as placing certain decisions of the courts and the regulatory authority[4] on a statutory footing.

The Act has elicited a predictably polarised response. 'Dignitarian' (Brownsword, 2008: 39-43) and 'bioconservative' (Hughes, 2004) opponents of reproductive and genetic technologies, such as preimplantation genetic diagnosis (PGD) and embryo research, bemoaned a triumph for amoral, technocratic priorities, and a defeat for democracy and respect for life. Josephine Quintavalle, of the pressure group Comment on Reproductive Ethics, opposed the Bill on the grounds that, if enacted, it would 'simply liberalise everything even further',[5] while the organisation's website responded to the Bill's eventual success with an article beginning 'Ruthless scientific imperative trumps morality yet again in the United Kingdom.'[6]

Though the Act certainly does contain 'liberalising' elements, it would be something of a stretch to characterise its overall tone as liberal. On the one hand, it dispenses with what many considered to be a gratuitously reactionary and divisive requirement that, in determining whether a woman should be assisted to become pregnant, attention should be paid to the need of the future child for a father,[7] substituting a reference to the 'need for a supporting parent'.[8] Other elements, however, merely formalise previous practice; the provision for the use of PGD to create what have become known as 'saviour siblings'[9] adds legislative force to what was already permitted under common law.[10] A third category of reforms move the law in a more restrictive direction; social sex selection is, for the first time, legally prohibited (the use of the technique for this purpose having previously been ruled out by the licensing authority, the HFEA,[11] but not by the 1990 Act.)

The 2008 Act is, then, a political compromise, containing both liberalising and restrictive elements. In Roger Brownsword's terms, the 'regulatory tilt' (2008: 21) in the United Kingdom is to be neither straightforwardly permissive nor prohibitive. Insofar as this 'mixed'

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3 Human Fertilisation and Embryology Act 1990.

4 The Human Fertilisation and Embryology Authority (HFEA).

5 'New human fertilisation and embryology bill –- dark days ahead for democracy and the ordre public', 10 November 2007, available at http://www.corethics.org/index2.php?d=press&item=20 (accessed 26 February 2010).

6 'Scientific imperative trumps morality' (4 November, 2008), available at http://www.corethics.org/index2.php?d=news&item=15 (accessed 26 February 2010).

7 Previously contained in Human Fertilisation and Embryology Act 1990, section 13(5).

8 Human Fertilisation and Embryology Act 2008, section 14(2)(b).

9 Schedule 2, paragraph 3(d).

10 R (Quintavalle) v HFEA [2005] 2 All ER 555.

11 HFEA Code of Practice, fifth edition, March 2001, paragraph 9.9.

approach reflects a plurality of approaches to a complex subject, it is, perhaps, to be welcomed. However, while legislation relating to such a complex area cannot satisfy all ethical perspectives, it is not, perhaps, unreasonable to expect that it at least engages with the most influential critiques and arguments. It is my contention that the 2008 Act is fatally undermined by a failure on the part of its drafters and supporters to confront certain fundamental questions of principle, a failure that risks rendering aspects of the new legislation as ethically incoherent as the previous regulatory regime.

I have previously argued (Gavaghan, 2007) that the pre-2008 regulatory framework, whereby the broad principles of the 1990 Act were interpreted and applied by the Human Fertilisation and Embryology Authority, routinely failed to consider the 'welfare of the child'[12] in the light of what is now a widely (though not universally) accepted understanding that determinations as to the future child's welfare cannot be disentangled from decisions about its identity. This perspective has at its core an insight that is both simple and, frequently, highly counterintuitive: that a decision to implant one embryo rather than another will result in the birth of one child rather than another. From here, it is but a short logical step to a related position that has particular significance to the regulation of assisted reproductive technologies (ARTs): in all but the rarest of cases, a child will not be *harmed* by its own creation. Or, to put it another way, it would not have been better off had a different child been born in its place, even where that other child would have had a healthier, longer, or happier life.

Yet, despite the growing body of commentary making this very point,[13] the 2008 Act shows a marked failure to engage with this concern. In particular, Section 14 (4) (9), which requires that embryos known to have a significant risk of 'serious physical or mental disability' or 'serious illness (...) must not be preferred to those that are not known to have such an abnormality', seems to fly in the face of the non-identity conclusion.

In this paper, I propose firstly that this clause displays a philosophical muddle on the part of the Act's supporters – a muddle that is, incidentally, likely to cause considerable offence to many disabled

[12] Section 13(5) of the 1990 Act stipulated that 'A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.'.

[13] See, for example, Glannon (2001) and Scott (2007).

people.[14] Next, I will engage with some recent attempts to answer the 'non-identity conclusion', attempts that – if successful – may render Section 14(4)(9) more ethically explicable. In particular, I will consider:

- the putative 'duty of procreative beneficence';
- the suggestion that 'the future child I have' could be thought of as a single entity, which can be benefited or harmed by identity-defining choices;
- the various species of Non-Person Affecting Harms, which argue for an impersonal utilitarian obligation to bring about the best aggregate outcome, regardless of whether any identifiable individual would have been harmed by the alternative course.

My suggestion, however, is that the Act no more does justice to these alternatives than to the non-identity conclusion; indeed, it displays scant awareness of the wide-ranging and rich philosophical debates that have surrounded these questions since before the first attempt to legislate on reproductive choices.

8.2. Background and Context

The notion that prospective parents should be prohibited from choosing to have disabled children may give rise to one of several responses. We may, for example, regard it as ethically correct that parents ought to refrain from such choices; such is the view expressed by Julian Savulescu in his argument for a duty of 'procreative beneficence' (2001), and by David Shaw (2008) in a recent article in *Bioethics*. I will return to this notion later, but the other reaction that may be provoked by Section 14(4)(9) is to wonder why it might ever be necessary. After all, surely we can, as Francis Fukuyama (2002: 92) has suggested, 'presume that parents will not seek to deliberately harm their children, but rather will try to maximise their happiness.

The concern that lay behind this particular prohibition was set forth in the Explanatory Notes to an earlier version of the Bill: 'This would prevent similar situations to cases, outside the UK, where positive selection of deaf donors in order deliberately to result in a deaf child have been reported.'[15] The situation referred to was presumably that concerning Sharon Duchesneau and Candy McCulloch, a couple in the

[14] For a recent example, see Rebecca Atkinson, 'I wouldn't have minded if my baby had been born deaf, but the embryology bill suggests I should', *The Guardian*, 10 October 2008.

[15] Explanatory notes on the Human Fertilisation and Embryology Bill as introduced in the House of Lords on 8 November 2007, para. 109, available at http://www.publications.parliament.uk/pa/ld200708/ldbills/006/en/2008006en.pdf. (accessed 26 February 2010)

USA who selected a sperm-donor who would maximise the chances that their future offspring would share their deafness.[16]

As a wave of controversy broke around the new Bill, the British media turned its attention to a UK equivalent of Duchesneau and McCulloch. Paula Garfield and Tomato Lichy are also Deaf, and also either want actively to choose, or at least not to be forced to reject (the media coverage is unfortunately ambiguous as to this vital point), a similarly affected child. That the Bill, and the Act it became, would appear to preclude them from doing so has led to it being described by some commentators as eugenic both in intent and in purpose. Indeed, a campaign was formed under the name StopEugenics, specifically to oppose Clause 14(4)(9).[17] This maintained that the Clause:

> is clearly a form of EUGENICS. Forcing parents to reject some embryos over others has no place in a democratic society. Clause 14(4)(9) creates a situation whereby, in law, the life of a Deaf person becomes of lesser worth than that of a hearing person, despite the Government's aim for a more equal society, through the new Commission for Equality and Human Rights.[18]

Although StopEugenics makes occasional reference to other conditions that the Bill may impact upon, such as those of 'restricted growth', their principal focus has been upon deafness. Indeed, it may be thought that, in selecting this example, the Government made a tactical error. Deafness is not unambiguously within the category of 'serious physical or mental disability'. Indeed, it is not unambiguously a disability at all; many within the Deaf community consider it a minority culture with, for example, its own language(s); as Tomato Lichy has argued, 'Being deaf is not about being disabled, or medically incomplete – it's about being part of a linguistic minority'.[19] Furthermore, the Deaf community has a strong tradition of political activism, with strong ties to academia and the media.

The ensuing backlash against the Clause may account for the removal of any reference to deafness in the Explanatory Notes to the final version[20] – though in terms of loss of trust from the Deaf

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[16] See Spriggs (2002).

[17] StopEugenics's website http://stopeugenics.org appears to be no longer accessible by non-members. The same provision is referred to as a Clause in the draft legislation, but a Section in the final Act.

[18] See http://www.grumpyoldeafies.com/2008/05/petition_against_1449_human_fe.html. (accessed 26 February 2010)

[19] See *The Guardian*, 21 March 2006.

[20] Paragraph 114 of the final Explanatory Notes reads: 'embryos that are known to have an abnormality (including a gender-related abnormality) are not to be preferred to embryos not known to have such an abnormality. The same restriction is also applied to the selection of persons as gamete or embryo donors. This would prevent assisted

community, the damage may already be done. Nonetheless, the general principle looks set to remain; where a choice is known to exist, prospective parents will not be allowed to choose to have a seriously disabled child instead of a 'healthy' child.

It should perhaps be made clear at this point that the Clause does *not* make it compulsory for those who know they are at risk of passing on a genetic disability to take steps to avoid so doing. A couple able to have children without technological assistance will not be subject to legal scrutiny. Furthermore, it seems that a couple having IVF or other reproductive assistance will be subject to no compulsion to have their embryos screened at all. Finally, agreeing to have embryos screened for one condition – say, cystic fibrosis – will not require a couple to agree to screening for another, like deafness or restricted height.

These limitations, however, do not insulate Section 14(4)(9) from criticism; indeed, as I will argue, it may be that the failure to require any of these positive steps further undermines the ethical basis of the Section.

8.3. The Nature of the Problem

Section 14(4)(9), then, serves only to prevent the creation or selection of a disabled embryo when an unaffected embryo could be chosen instead. It does not force couples to use techniques like preimplantation genetic diagnosis (PGD) – those who prefer to take their chances with what are referred to in Andrew Niccol's film *Gattaca* as 'faith babies' will still be free to do so. And it does not present an obstacle to couples who are faced only with a choice between 'disabled embryos'.[21] It is my contention, however, that it is still ethically problematic.

The problem derives from a series of observations about the relationship between reproductive choices and identity. Derek Parfit's (1984: 358) thought experiment (now near-legendary in bioethics circles) invited the reader to consider two situations. In one, a 14-year-old girl decides to become pregnant.

> Because she is so young, she gives her child a bad start in life. Though this will have bad effects throughout the child's life, his life will, predictably, be worth living. If this girl had waited for several years, she

reproduction technology being used to select an embryo with a view to increasing the chance of giving birth to a child that had or would develop a serious medical condition, or to select a donor to increase the chance of a child having a serious medical condition.' Hence, no specific examples of what might be regarded as a 'serious medical condition' are identified.

[21] Of course, it is not the embryos that are disabled, but the children they may become. The term, however, serves as convenient shorthand.

> would have had a different child, to whom she would have given a better start in life.

At first glance, it may seem as though the girl would do better to delay pregnancy; to do otherwise, after all, would be to deny her future child 'a better start in life', and to do this, we might think, is to harm the child.

Perhaps an even starker example is presented in the imagined case of a woman who is, for a short period of time, taking a course of medication that would cause disability in any child with whom she became pregnant. If she delays pregnancy until the course of medication is complete, she will be able to conceive a healthy child. Again, our first intuition will probably be that she would be acting unethically if she does not delay pregnancy; what is a short delay when weighed against the prospect of inflicting disability on a child?

The problem with both intuitive responses is that they ignore a vitally important question: if either the girl or the woman decides to become pregnant now, who precisely will be made worse off? Delaying conception – for years or for months – may result in the birth of a healthier, even a happier child. But it would be a *different* child, a child created by the fusion of a different egg and a different sperm.[22] What both the girl and the woman would be doing, then, is not improving the life of a particular child, but in effect replacing that child with another – albeit healthier – child.

The success of this argument relies on acceptance of what Bernard Williams (1990: 169) has referred to as the 'zygotic principle'. This maintains that

> the identity of human beings, as of other sexually reproducing creatures, lies in the union of two given gametes: if either the sperm or the ovum or both had been different, a different human being would have been formed and born.

Identity, of course, is a complex and controversial subject, in philosophy, psychology and a range of other disciplines. In claiming that a different combination of gametes would lead to a different child, it need not be asserted that genetic origins are the most important, still less the only, factor on which personal identity depends. Nonetheless, the (I think, plausible) contention on which this approach rests is that

[22] Of course, different questions would arise if the choice was to delay implantation of a cryo-preserved embryo. In that case, whether the pregnancy was commenced earlier or later, the resulting child would be genetically identical. The question of whether the child brought up by a 14- or 15-year-old mother would develop into 'the same person' as in the situation where s/he were brought up by an older mother, while intriguing, will not be addressed here, as this issue does not arise in the context of statutory provision under discussion.

replacing one or more of the gametes[23] from which an embryo is created is *one way* of altering the identity of the child which results.[24] Parfit referred to this apparent paradox as The Non-Identity Problem; I will opt instead for the more neutral Non-Identity Conclusion, as this does not beg the question as to whether Parfit's conclusion should in fact be regarded as ethically or logically problematic. What seems undeniable, however, is that his conclusion is problematic for Section 14(4)(9) of the 2008 Act. Parfit's approach would mean that the choice envisioned in Section 14(4)(9) is not simply between disability and 'normal' health, but between two distinct children that could result. If the couple elect to implant an embryo affected by genetic deafness, that will (if it develops into anything at all) develop into a deaf child. But for that child, the option of a life with hearing was never an option. Quite simply, the only alternative to deaf life was no life at all.

Garfield and Lichy, then, wish to make a deaf child, not make a child deaf. Unless we can, with some confidence, predict that the deaf child's life will be so blighted as to allow us to say it would have been better never born, it cannot be said that their decision is in any sense contrary to the resulting child's interests.[25]

Similar responses can be offered even in the face of more unambiguously disabling conditions, such as muscular dystrophy or cystic fibrosis; unless it is likely that these conditions will impact so strongly on the child as to inflict upon it a 'life worse than death',[26] it is impossible to argue that this child has been harmed by not being replaced with a healthier alternative. The consequences of this realisation are both profound and counter-intuitive. Parfit himself found the conclusion hard to accept. Philip G. Peters, Jr. (1999: 384-385) has asserted that the Non-Identity Conclusion 'assaults our common sense' and 'simply do[es] not pass a moral gut test', while

[23] Parfit, in fact, seems to have believed that both gametes must be different before we can speak of a wholly different person. This is implicit in his statement that '[i]f any particular person had not been conceived within a month of the time when he was in fact conceived, he would in fact never have existed' (1984: 372), the implication being that both sperm and ovum must be different. This seems to beg the question as to how much genetic difference is required before we can speak of a 'different person'. Would a child conceived of the same ovum but a different sperm be sufficiently similar to constitute, in some sense, the same person as the child that would have been conceived a few hours or days earlier?

[24] But for a very different approach to the subject of personal identity, see Gillett (2008).

[25] The alternative, hearing child, of course, cannot have been harmed, as it never became more than a possibility.

[26] This paper will not consider the question of whether any life could be said to be worse than death, but at most we would be talking about a very few, extremely severe conditions. Jonathan Glover's (2001: 431) description of Dystrophic Epidermolysis Bullosa suggests that, at least in some cases, it may fall within this category.

Margot Brazier has claimed that it 'sounds very good' but 'means very little'.[27]

With respect to Professor Brazier, the conclusion may be mistaken, for if it is intellectually sound, it must surely mean a very great deal. But are we in fact forced to accept this conclusion? Since Parfit posed the problem a quarter of a century ago, numerous attempts have been made to offer alternative approaches to the identity issue. Could it be that the drafters and supporters of Section 14(4)(9) were persuaded by one or more of those attempted rebuttals?

My suggestion is that, although often thought-provoking and interesting, none of the alternatives to the non-identity conclusion have been wholly successful in offering a more plausible account of our reproductive responsibilities. In the next section, I will attempt to explain why I believe they have failed, before concluding by showing that, even if they offer a compelling response to Parfit, they do not account for the specific direction UK law seems to have taken.

8.4. Person-affecting Arguments

This species of reply is characterised by a shared belief that an obligation to make particular choices derives from a concern for the welfare of *the resulting child*. There are several versions of the person-affecting claim, but broadly they can be generalised under what Julian Savulescu (2001) has called a *duty of procreative beneficence*. Thus, as Nicholas DeLacy-Brown has averred, 'the future child is owed a duty by which the most positive outcome is chosen by its parents.'[28] A somewhat more limited version of the putative duty is espoused in a recent article by David Shaw (2008: 412-413): 'When a choice is available concerning our future children (...) although we do not have an obligation to 'perfect' them as in the superhuman example, we do have an obligation to avoid harm. And deafness *is* a harm.'

Indeed, the version of the principle espoused by Savulescu (2001: 415) would seem to go some way beyond the remit of s.14(4)(9), requiring that

> Couples (or single reproducers) should select the child, of the possible children they could have, who is expected to have the best life, or at least as good a life as the others, based on the relevant, available information.

As he makes clear in the article, Savulescu (2001: 414) would not restrict the principle to what are conventionally regarded as disease

[27] Oral evidence to the House of Commons Select Committee on Science and Technology, Q880.

[28] DeLacy-Brown, N., *BioNews*, 27 July 2007.

states; rather, he specifically argues for 'a moral obligation to test for genetic contribution to non-disease states such as intelligence and to use this information in reproductive decision-making.'

How, though, do proponents of such a duty answer the non-identity Conclusion? How do they explain *which* child is owed the beneficent duty? Neither Savulescu nor DeLacy-Brown offer such an answer, at least in the articles cited here. Other writers, however, have attempted some fairly ingenious arguments. The 'generic child' view, for example, relies on thinking not about the array of possible children that could result from a 'genesis decision', but thinking instead in terms of what will be best for 'the child I will have'.

Robert M. Green is one writer who has sought to attribute interests to a 'generic' child, a sort of composite of all the possible children our hypothetical prospective parent might have had (1997: 8):[29]

> before conception (for most people) and even following conception during early pregnancy (for many others), lives are in a sense 'fungible'; they are interchangeable generic units, rather than identifiable and unique. Parents intending to have a child do not imagine the identifiable child 'Mary' who they come to know in the years following her birth, but a 'generic' child with qualities like those of most other children being born in its cohort. It is this imagined child whom they usually have in mind in choosing to have a child in the first place, and against whom they and others measure the actual condition of the real child when it is born.

If it is intelligible to speak of a single 'generic child', then it is perhaps intelligible to attribute to that child a unitary set of interests; and it may be intelligible to include among those interests something like an 'interest in being born in the best possible genetic health', or perhaps an 'interest in being born with a minimum standard of genetic health'.

Such a view certainly has an intuitive appeal. Though Green offers no evidence for his claim, it is not implausible that many prospective parents do in fact think in such generic terms, and make certain decisions on that basis; I can decide to buy a house with a large garden, or in an area with a good school, because that will probably be best for my future child, *regardless* of who that future child will be.

Procreative decisions are somewhat more difficult. The decisions about gardens and schools make sense because I can predict that, whatever child I may have, it will probably have interests that are advanced by having these facilities to hand. But they are not decisions about the identity of that child. In the same way, my department may advertise for a new professor. Knowing that the role will, some day, be filled, it may refurbish the office he or she is to occupy; whatever

[29] For a similar argument, see Simo Vehmas (2002: 52-53).

candidate is successful, s/he will probably prefer a draft-proof window and a roof that doesn't leak. This decision, though, is obviously distinguishable from the decision as to who gets the job.

In the former context, it is sensible to group together the interests of the various candidates into one, notional entity, *the eventual professor*, and to make decisions that will predictably benefit that person. But can the *choice* of who is appointed really be made in the interests of that notional entity?

Another difficulty with the generic child approach lies with ascertaining which interests precisely can be attributed to that entity. Decisions about which embryo to implant directly affect not only what child, but what *kind of* child will be born. And as genetic knowledge grows, it may be possible to determine certain character traits, temperamental dispositions, even tastes that the future child will possess. Thus, one embryo may be disposed to develop into a lively, energetic child with a low attention span, while another will be withdrawn and studious. A third candidate may be affected by a significant cognitive impairment whereby his interests will be very different again.

Is it possible, we might wonder, to make a decision based on 'the interests of the future child' when the content of that decision will determine not just whether those interests are satisfied, but what those interests will be?

A further possible objection to the 'generic child' view is illustrated by the following scenario. A couple who are both genetically deaf elect to use PGD in an attempt to avoid a deaf child. They create a number of embryos, but PGD reveal that all are homozygous for the gene, and therefore all will become deaf children. The couple are determined to have a child, and are on the point of telling the clinic to proceed anyway, when they are offered an alternative. Another (non-deaf) couple being treated at the same clinic were successful with their first attempt at IVF. As they do not want any more children, they have donated their remaining in vitro embryos to be donated to other infertile couples.

Should the deaf couple accept the non-deaf donated embryos? A concern for the 'generic child' that they may have would seem to suggest that they are ethically duty-bound to do so. If Shaw is right, and deafness is a harm, it is a harm that can be avoided by accepting the donated embryo instead. If the couple insist that they would rather implant an embryo created from their own gametes, they are electing to harm their future child. Furthermore, the future, deaf child would seem to have a legitimate complaint against his parents, a justifiable protest

that 'he' need never have been deaf had they only chosen the donated embryo instead.[30]

Of course, the generic child approach could potentially be salvaged by adding some clause such as 'Couples (or single reproducers) should select the child, of the possible children they could have *from their own gametes*, who is expected to have the best life'. This would mean that the deaf couple who elect to implant their own, deaf embryo would not have acted wrongly, if the only alternative was to implant someone else's non-deaf embryo. But such a caveat seems to involve the belief that the parents' interest in creating their own genetic offspring is sufficiently compelling as to outweigh their duty of beneficence to the resulting child. Elevating their own interests in a child of a particular kind above the interests of that child is precisely what has led to criticism of Duchesneau and McCulloch, or Garfield and Lichy. If it is ethically wrong to create a harmed child in pursuit of their own preferences, then presumably it is wrong regardless of what those preferences might be; that a preference for genetically related offspring is (plausibly) more common than a preference for deaf offspring is surely insufficient to distinguish the two cases.

The 'generic child' approach, then, might be thought artificial in that it seems to involve conflating the interests and the identities of several different potential future children; and it might be thought to be unduly burdensome, in that it seems to involve an imperative to implant a donated embryo (or using donated gametes) where that embryo seems likely to have a better quality of life than any genetically related alternative.[31]

8.5. Non-person Affecting Approaches

Not all responses to the Non-Identity Problem have stayed within the person-affecting paradigm. Indeed, Parfit himself considered another class of ethical concerns that may avoid the counter-intuitive claim that choosing a disabled child harms no-one. As distinct from the arguments considered in the previous section, these focus not on the interests and rights of particular people, but on a putative impersonal

[30] If the possibility exists that a future child would sustain more harm from the knowledge that the people who raised him were not genetically related than from the fact of deafness, the point can be salvaged by substituting a more serious genetic condition in place of deafness. Could the knowledge of being 'adopted' really be more detrimental to a child's interests than having a condition like cystic fibrosis?

[31] For Shaw, the duty of procreative beneficence merely requires that disability is avoided, but for Savulescu, as we have seen, the duty encompasses any choice that may improve the resulting child's quality of life. This would seem to require accepting not only a non-disabled donor embryo, but any embryo that is likely to become a more intelligent, attractive, athletic, etc. child.

duty to maximise good consequences. Jonathan Glover (2006) and John Harris (2007) have both recently espoused versions of such non-person-affecting approaches to such questions. These are varieties of what are sometimes called maximising consequentialist approaches, according to which we should make choices that make the world a better rather than a worse place, even if no particular people would have been harmed by the alternative choices.

Arguably, a distinction may be thought to exist between positive and negative versions of this duty. Hallvard Lillehammer (2005: 26) refers to an impersonal variation on the 'beneficence principle', according to which 'where we can choose between producing more benefit rather than less, we should produce more. Thus, in preconception cases, prospective parents should act so as to produce as much benefit for any prospective children as possible.' Joel Feinberg, on the other hand, has written in terms of 'wantonly introducing a certain evil *into the world*, not for inflicting harm on a person' (1194: 103). The terms employed by Feinberg seem to point to a duty of non-maleficence rather than one of beneficence, according to which there is a wrong in causing suffering even if no person loses out on balance.

Every (sentient) life, though, involves a degree of suffering; surely the duty cannot be to avoid *all* suffering, as this would seem to imply that no-one should have *any children at all*.[32] Feinberg, of course, talks about *needless* suffering. But when, we must ask, is suffering really 'needless'? In procreative choices, a degree of suffering is a pre-requisite for the existence of the children who are actually born. If he means 'needless' in the sense of 'avoidable for this child', then suffering in such cases is not needless. If, on the other hand, he means 'needless' in the sense of being 'avoidable at all', then we are back to the earlier point, that *all* suffering could be avoided if – but only if – we refrained from having children at all.

More plausible accounts of a non-person-affecting duty involve balancing harms and benefits. On this account, we discharge our duty when we act so as to maximise the balance of benefit over harm; having a child with a handicapped life would, therefore, be ethically acceptable provided that (a) its life still contained a balance of satisfaction over suffering, and (b) there was no alternative course of action open to us that would have produced a greater net gain in utilitarian terms. So, if Garfield and Lichy could *only* have deaf children, they would do nothing wrong if they had a deaf child; as Harris (2007: 108) has written, 'for those who can only have children with disabilities,

[32] Precisely this argument has been made by David Benatar in *Better Never to Have Been* (2006).

having such children may well be morally better, for the parents and for the children, than having no children at all.'

One possible difficulty with this view is that is that it still seems to require the acceptance of a donor embryo, where that embryo will predictably lead to a better life than one that is genetically related. Of course, the parents loss of happiness in not being able to have their own genetic offspring would also have to factored into the felicific calculus, but we could readily imagine this being outweighed, on balance, where the disability avoided was fairly serious.

A second difficulty with this view is that it seems to impose far greater obligations than those envisaged by its proponents. If we are obliged to contribute to the collective pot of human happiness by having the 'best possible children', what does this say about those of us who choose to have no children at all? Surely, we have failed in our duty to a greater extent than someone who merely has a less-than-optimally happy child, which nonetheless makes a positive contribution to the collective utility pool. To say otherwise seems analogous to saying that, while we have no obligation to give anything to charity, those who contribute a bit are duty-bound to contribute as much as possible.

And the duty would not merely be to reproduce, but presumably to reproduce until such point that an additional child would actually detract from, rather than contribute to, the balance of happiness-over-misery in the world, perhaps because of overcrowding or competition for scarce resources.[33] Neither of these conclusions, it must be acknowledged, is inherently illogical; nor, perhaps, are they obviously repugnant. Impersonal duties to 'the world' may not be ethically incoherent. However, insofar as they lead to obligations to reproduce, or to accept donor embryos or gametes instead of producing one's own genetic offspring, non-person affecting approaches seem likely to take us to places that are at least as intuitively unappealing as the non-identity conclusion, to which they are supposed to provide an alternative.

8.6. Conclusion

My suggestion, then, is that what Parfit referred to as the Non-Identity Problem may not be such a problem at all. At least, it is no more problematic than the alternatives that have been proposed. The 'generic child' view seems to rely on the artificial aggregation of

[33] Christian Munthe (1996) has argued that the act of procreation in fact constitutes an inefficient use of resources which could, from a maximising consequentialist view, be better spent improving the lives of existing persons with wretched lives.

disparate interests around a merely notional being. The non-person affecting approach, while coherent on its own terms, seems to impose duties to create new lives *ab initio*. And both seem to require that a donor embryo or gamete should be accepted where the result will predictably be a child with a better quality of life.

My preference, as I have argued elsewhere, is for an approach guided by the Non-Identity Principle, whereby the law would concern itself only with choices likely to result in 'worse than nothing' lives – i.e. lives that could plausibly cause a harm on balance to the resulting child. Neither of the alternative approaches, though, is entirely without merit, and while I may have succeeded in demonstrating some of their less palatable consequences, I do not pretend that I have in any way *proved* the superiority of the non-identity conclusion. It is perhaps interesting, then, to consider what the new Act would look like if UK legislators had been guided by either of these alternative principles.

Both 'generic child' and maximising consequentialist approaches would certainly take a dim view of a conscious decision to implant an embryo with a significant risk of a 'serious physical or mental disability' or 'serious illness', at least where the option exists to implant an alternative embryo 'not known to have such an abnormality'. But would they stop there? The Act, it should be remembered, does not impose any duty to have embryos tested prior to implantation at all. It does not even require that an embryo being tested for one condition should be tested for others of which the couple are known to be carriers.

This seems to imply that what s.14(4)(9) is primarily concerned with is preventing the deliberate creation of disabled children. A regulatory framework predicated upon duties to generic future children, though, might be expected to go further, requiring prospective parents to take positive steps to avoid significant impairment. At the very least, when PGD is being carried out anyway, it would require embryos to be tested for significant disabilities or illnesses of which there is a significant risk, with the additional requirement that those free from such impairment must be preferred for implantation. Parental choice, after all, is rarely accepted in law as a justifiable reason for denying remedial treatment to born children. If the future child is to be thought of in terms of a unitary entity with a singular identity, then why should the law permit its parents to deny it beneficial 'treatment', any more than it would allow them to deny it to any other child?

What of the non-person affecting approach? Again, it seems that if the Act's drafters and supporters were motivated by such maximising consequentialist concerns, they would not stop at prohibiting the conscious decision to select an impaired embryo, but would actively require embryo testing prior to implantation, allowing only those with the best chance at the happiest life to be implanted.

Furthermore, in line with Savulescu's approach, this would seem to imply that selection decisions should be informed not only considerations of disability and illness, but by whatever is known about traits that will predictably lead to a happier life. Savulescu gives the example of a good memory, but we might consider athletic prowess, musical ability and even conventional attractiveness as plausible candidates for selection criteria. The Act, however, does not only stop short of requiring such factors to be considered, it actually prohibits testing for such non-disease traits. Schedule 2 limits the uses of embryo testing to the following circumstances:

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,
(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,
(c) in a case where there is a particular risk that any resulting child will have or develop—
    1. a gender-related serious physical or mental disability,
    2. a gender-related serious illness, or
    3. any other gender-related serious medical condition, establishing the sex of the embryo.[34]

This restriction certainly does not derive from the non-identity position, but neither the generic child nor the non-person affecting approaches seem to fit easily with it either. If there are other ways of benefiting the future child, or of adding to the aggregate happiness in the world, apart from avoiding disease traits, why should these not be, at very least, permitted?

A recent argument from Katrien Devolder and Thomas Douglas contends that reproductive decisions should be guided by a principle of Wide Procreative Beneficence, whereby the choices of prospective parents should be guided by considerations of benefit to third parties, and to society, as well as 'individualistic' concern for the resulting child. They provided examples of disinclination towards violent aggression, or eating red meat, as traits that would predictably benefit society. While not unproblematic, this suggestion at least seems to be consistent with a utilitarian concern with maximising good outcomes, rather than a

[34] A couple of additional exceptions are permitted for identifying an embryo that will be a tissue match for an existing child – the so-called 'saviour sibling' scenario – and for resolving situations of uncertainty as to which embryo belongs to which gamete donors. These, however, are not relevant to the present discussion.

somewhat arbitrary principle of avoiding certain sub-optimal outcomes.[35]

Shaw has (2008: 409) argued that 'from the point of view of the beneficence principle – we should try to create more benefit rather than less – this is true. But we do not have an obligation to enhance our children beyond the norm, and an impartial perspective can easily accommodate an obligation to avoid harm (the nonmaleficence principle) without an accompanying obligation to provide benefit beyond the norm.' There may be other reasons why enhancement is more problematic than avoiding illness or disability (though as Harris has argued (2007), this distinction is far from easy to draw or straightforwardly relevant), but it is not obvious why a maximising consequentialist would regard increasing the pot of human happiness by avoiding harm to be more worthwhile than achieving the same outcome by promoting benefit.

In trying to find a 'middle way' between those who believe PGD to be morally mandatory (though it should be noted that neither Savulescu nor Harris believe it should be *legally* compulsory) and those who would prohibit it outright, the UK Government seems to have alighted on an approach that avoids any of the profound ethical questions asked of genesis decisions, and of the previous legislation. The new legislation appears not to be informed by the Parfitian non-identity conclusion, but neither does it do justice to either of the alternative models I have considered. Instead of promoting a 'best outcome' approach – for the future child, or the world in general – the legislation focuses on normal functioning. Yet it stops short even of requiring steps to achieve this, outside of the particular – and thus far very rare – scenario of a couple who wish *deliberately* to create a disabled child.

The non-identity conclusion – my own preferred approach – maintains that there is no ethical problem with choosing for or against disability, or for that matter refusing to make any choice at all. The 'generic child' and the non-person-affecting approaches, in contrast, would seem to regard the avoidable creation of disability/ harm as wrong, whether that was by a positive choice of a 'disabled embryo' or a refusal to use technologies like PGD or (as a last resort) donor gametes or embryos. Whichever approach is preferred, however, it is difficult to understand the ethical basis for the particular limitations placed on reproductive choice by the 2008 Act.

[35] Paper presented by Katrien Devolder, Ethics After Harm conference, University of Otago, January 2010.

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Chapter 9. Law at a Crossroads: Losing the Thread or Regaining Control? The collapse of distance in real-time computing

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Abstract
Control at a distance (cybernetics) has been one of the achievements of modern law. Since the advent of the printing press, written law has been instrumental for those in power to rule over a large jurisdiction with a great many subjects: enabling sovereign power to rule *by* law. Moving from absolutism to the rule *of* law basically meant that law gained a measure of autonomy between ruler and subjects, still providing the means to govern but also providing individual citizens with legal instruments to resist those in charge. This chapter argues that both the rule *by* law and the rule *of* law have been an affordance of the printing press, extending the distantiations in time and space already inherent in the script, thus exponentially reinforcing the need for interpretation and the related delays and hesitations that precede the application of law in court. Looking into the novel communication infrastructures we can observe a shift from the linear sequential thought processes particular to the age of the printing press to the parallel processing typical for the era of real time computing. We argue that this shift enlarges the scope for virtualisation (computer mediated real time modeling and simulation), but simultaneously collapses the distantiations implied in the logic of the script, washing away the need for reflection that is preconditional for critical reasoning as well as for a fair trial. Speed and instantaneity are replacing delay and distance as pertinent features of communication. We then argue that lawyers must urgently align with computer scientists to advise the legislator on how to redesign the emerging socio-technical infrastructure in a way that affords the central tenets of constitutional democracy. Building on the concept of Ambient Law this means that the democratic legislator must become involved in articulating the necessary safeguards into the socio-technical infrastructure these safeguards aim to protect against.

9.1. Introduction

The question I want to raise in this chapter – and to which I have only the beginnings of an answer – is how we can sustain the legal protections based on the technologies of the script and the printing press, in the face of an epistemic shift towards a digital age. This shift threatens to collapse the distance needed for the contestation of the way we are being profiled and treated.

Some of the crucial protections provided by modern law, notably privacy, non-discrimination and due process, may be an affordance of the socio-technical infrastructure of the printing press. This can be explained by the fourfold distantiation inherent in the script as described by philosopher Paul Ricoeur (section 2). The reinforcement of this distantiation, brought about by the printing press, evoked the need for interpretation, which in turn generated the built-in hesitation and delay of the fair trial, thus creating a space and time for the contestation of dominant frames of interpretation (section 3). The shift from the script and the printing press to the digital era provokes an epistemic shift that magnifies what cyberphilosopher Pierre Lévy has called the *virtualisation* that was already enabled by the printing press, while – with the advent of web 2.0 and web 3.0 – this virtualisation paradoxically threatens to collapse the distantiations afforded by the script and the printing press (section 4). The reason for this paradox seems to be that though the world wide web exponentially increases geographical distantiations, it moves towards a continuous real time synchronization that collapses the distance in time.

The collapse of distance is triggered by the increasing usage of Web 2.0 technologies (or Social Networking Sites, SNSs in short), and a simultaneous explosion of multitasking, especially in the generation that has grown up with web 1.0 and 2.0. The mind of what Palfrey and Gasser (2008) call 'digital natives' is no longer equivalent with the linear-sequential mind of what I would call the 'bookish digital immigrant': authors like Tapscott (2009) actually speak of a cognitive structure geared to instant parallel processing and multitasking, favouring speed and pertinence rather than the hesitation and delay of the printing press era. It seems that though digital natives' capacity for 'scrutiny' is impressive, it is based on parallel processing and is wary of cumbersome linear thought processes. It does not seem to equate with the critical thinking typical for the bookish mind.

The collapse of distance, described in section 4, is further elaborated in section 5, and related to the emergence of a new sense of time-space, often called 'real time', conflating distance in time and space to a new kind of synchronisation, afforded by the new technological infrastructure (global communication and mobility across different time zones, immediate access to unprecedented amounts of machine readable content). The problem is that the condensation of space-time inherent in real time communications and interactions renders invisible that communication and interaction is always a matter of interpretation, a fact that is apparent when using 'slow' technologies like the script or the printing press. As interpretation becomes less visible or even invisible, the scope for reflection and contestation is

diminished if not annulled, thus favouring the dominant or customised frames of interpretation supplied by the digital environment.

9.2. The Law and the Script: Control at a Distance

If we follow Lawrence Lessig (1999: 3) in defining cybernetics as 'control at a distance by devices' the most interesting device for control until the advent of computers has been the script, especially since it aligned itself with the law.[1] In fact, politically speaking, control at a distance has been one of the achievements of modern law. Harold Berman's encompassing history of *The Western Legal Tradition* (1983) demonstrates how the use of written legal texts that were imposed *as law* by the popes and later by the kings, enabled them to rule over a vast congregation, people or territory, especially in combination with the peace of God that stood for the beginnings of a monopoly of violence. Berman traces the epistemic shift from a predominantly oral legal tradition that is grounded in adjudication to a written legal tradition that is based on the competence to legislate. Whereas oral traditions depend on a mediative trial (Salas, 1992; Glenn, 2006; Berman, 1983; Collins and Skover, 1992) in which the judge has to win the cooperation of the parties because there is no state authority to back the verdict, written traditions usually coincide with the beginnings of statehood, developing codes that can be used in courts even if they initially only claim to summarize the unwritten oral law of the people whose legal habits they depict (for instance the *leges barbarorum*). By assigning scribes to the task of codifying the oral laws of their people, and subsequently requiring judges to apply these codes, the kings got a grip on the life of their subjects, even if the 'control' they intended was moderate and depended on a subtle balance of power between subjects, lords and overlord.[2]

Building on anthropology, history and media studies (Goody and Watt, 1963; Ong, 1982; Berman, 1983; McLuhan, 1994 (1964); Eisenstein, 2005 (second edition)), several legal scholars have described the impact of the transition from orality to the scribal age to the printing press on legal institutions (Berman, 1983; Katsh, 1995b; Katsh, 1995; Hildebrandt, 2002; Glenn, 2004; Hildebrandt, 2008), extending their analyses to the potential impacts of the transition to the digital era (Collins and Skover, 1992; Katsh, 1995b; Katsh, 1995a;

[1] Lessig may be wrong, because Norbert Wiener (1965), who coined the term in 1948, was perhaps more involved in how systems monitor and control themselves.

[2] The overlord or suzereign initially did not have any jurisdiction over the subjects of his vassals (the lords of the land).

Glenn, 2004; Hildebrandt and Koops, 2007; Hildebrandt, 2008).[3] Some of the authors offer detailed analyses of the institutional transitions within Anglo-American law, based on well known insights of media studies, discussing the implications of hypertexting and the changing speed of communication and information exchange across vast distances, for instance pointing out the way this may affect the role of precedent as typical for the age of the printing press (Katsh, 1995b).[4] My own interest is more focused on the *epistemic* implications of novel technological infrastructures, building on philosophers of technology, like Ihde (1990; 2002) and cyberspace philosophers like (Lévy, 1990) and (De Mul, 2003), steering free from the Scylla of technological determinism as well as from the Charibdis of social determinist constructivisms.

One of the most salient analyses of the epistemic shift from orality to the script, has been made by Paul Ricoeur (1986), who has written extensively on time, narrative and human identity. Ricoeur (1986) depicts a fourfold distantiation (Geisler 1985).[5]

First, the script literally inscribes into matter what was in the mind; it fixates what was ephemeral on clay tablets, into stone, and later on paper and screen (though we may wonder to what extent this is still fixed). In externalising and fixing thought, the volatility of the spoken word is suspended. Paradoxically the attempt to fixate a calculation or a story leads to a *distantiation of the meaning* of what is written, because the text can change hands and be read beyond the presence of the author. This distantiation of meaning generates a need for interpretation, because in the absence of the author the reader can never be sure what the author meant.

Second, the script liberates what is written down from the custody of the author, because even after his death and beyond his reach the text can be read and acted upon. This entails the *distantiation of the author* that initiates the need for interpretation and creates a situation in which the context of the reader co-determines the meaning of the text. This does not imply that the meaning of the text is now determined by the reader's response only, as the reader will communicate with others

[3] I thank Dan Burk for referring me to several US authors on this subject: in particular Collins and Skover (1992), Katsh (1995a) and Katsh (1995b).

[4] For a skeptical review of the US authors see Ross (2002), who criticizes what he calls high-level generalizations and a lack of attention to the social and political embodiment of such technologies, which can mute or reinforce whatever 'logic' seems to inhere in a particular technology. For relevant insights into the way technologies mediate human perception and behaviours see Ihde (1990; 2002) and Bijker and Law (1994), stressing what some call the social shaping of technologies. I would refer to Ihde (2008) in saying that while we are busy inventing technologies, our technologies also invent us.

[5] Geisler refers to John B. Thompson (1981) and to Paul Ricoeur (1978; 1981).

and be constrained by their interpretation, especially by the constraints produced by the network of texts that cross reference each other.

Third, the script enables a shift from ostensive to non-ostensive reference. A reference is ostensive if it refers to a shared *Umwelt*, presuming that whoever speaks and whoever listens are both present during the conversation and thus capable of pointing directly to things in their environment. Words like 'that', 'here', 'now', 'those people', 'you' are deictic terms that presume simultaneous presence of a speaker and whom she addresses. The script affords a *distantiation of ostensive reference*, opening a space and time not present, creating a *Welt* that is distinct from the *Umwelt*, allowing for a virtualisation from the actual in which we are implicated. Again, this generates a need for interpretation, precisely because we are reading about what is not present, what cannot be touched, pointed at, smelled or seen.

Fourth, the script enables a virtually unlimited audience to be addressed, thus creating a virtual – invisible, undetermined – public that is extended geographically (in space) and historically (in time). This depicts the *distantiation of the audience*, again producing a need for interpretation, because the con-text of the text changes as it travels to other interpretive communities.

This fourfold distantiation can be connected with a similar process of distantiation in the constitution and application of the law. As the law is written down, fixated, externalised and objectified its meaning becomes more fragile, open to discussion; as the author of the written law (the legislator and the judge) has less control over how his words are being read, those who read and speak the law need to develop techniques to stabilise the meaning in the face of the many ways it can be read; as the written law is no longer tied to a shared *Umwelt* it can become cross-contextual and more abstract; as the audience of the law extends it becomes possible to enlarge the scope of a jurisdiction, allowing for a much larger scope of control (at a distance).

In the next section we will see how this fourfold distantiation is reinforced by the invention of the printing press, which multiplies the distantiation in both time and space, creating a host of new possibilities for control and a host of new problems inherent in control at a distance. Moreover, as I will argue, the fragility of the written text that is inherent in the distantiation it encompasses, creates a vulnerability for those who rule by law, as they can never be sure how their law will – at the end of the day – be interpreted and applied.

9.3. The Law and the Printing Press – Authority and Contestation

Since the advent of the printing press, written law has been instrumental for those in power to rule over a large jurisdiction with a great many subjects: enabling sovereign power to rule *by* law. The germs of this sovereign power can be traced in the distantiation in time and space made possible by the script, but the printing press multiplied the effects of this distantiation in an exponential way. This afforded the shift from suzereignty to sovereignty, which entails a transition from a fragile reciprocity between feudal lords and their overlord to a firm grip by the overlord on his vassals and their subjects, eventually ruling out the difference between them – as they all ended up as subjects of the sovereign. The printing press allows the sovereign to construct a layer of loyal administrative servants who can be instructed on the basis of copies of the same text, thus affording the growth of a bureaucracy capable of ruling all those that fall within the jurisdiction of the administration, all based on the multiplication of printed text. The absolute king thus rules *by* law, using the law as an instrument of control at a distance, keeping tight control over its application by the emerging administration, but also keeping the lid on the royal courts that adjudicate on the meaning of the law *in the name of the king* (*rex lex loquens*, the king speaks the law). This rule *by* law is basically a rule by man, not to be confused with the rule *of* law. Rule by law continues as long as the king is the ultimate arbiter of what the law means in individual cases, due to his power to intervene in case law, casting aside a judge who contest the King's desired interpretation of the law.

While the sovereign rule *by* law is an affordance of the printing press, this technology also contains the affordances for a rule *of* law to come about. The sheer volume of texts that can be published, read and discussed produces an unprecedented amount of what we would now call legal information: laws, decrees, case law, restatements, doctrinal treatises, handbooks, scholarly explorations that all refer to each other, trying to accomplish the task of safeguarding legal certainty. This then produces a class of professional lawyers who appropriate this task of reconstructing the vast body of law in order to sustain its coherence, legitimacy and effectiveness. This class practices indexing, systemisation, rationalisation and coherent intertextual reference, resisting the influence of those not skilled in the workings of the law, whether they are kings, clergy, nobility or merely subjects. In caring for the coherence, legitimacy and effectiveness of the law, the lawyers end up giving birth to the law as an autonomous socio-technical construct, woven out of the body of interrelated legal texts whose meaning can no longer be decided upon by a single person. This historical artefact does

not present us with an absolute but a relative and not an introvert but a relational autonomy, distinguishing as well as connecting law, politics and ethics. The autonomy of the law is the product of the fourfold distantiation triggered by the script and its exponential expansion by the printing press. In putting it this way, I don't mean to suggest that there is a causal or deterministic connection between the printing press and the autonomy of law. Technologies have certain affordances (Gibson, 1986), they trigger certain behaviours (Lévy, 1990), they make possible what was not possible before and/or rule out previous habits of thought and action. I would say that they are constitutive or regulative of our behaviour patterns rather than arguing that they cause them (Hildebrandt, 2008). The language of cause and effect claims too much and clarifies too little.

The most salient demonstration of the birth of the autonomy of the law is Chief Justice Coke's remonstrance against absolutist King James I's attempt to interfere in the application of the law:

> Then the King said that he thought the law was founded upon reason, and that he and others had reason as well as the Judges: to which it was answered by me, that true it was, that God had endowed His Majesty with excellent science, and great endeowments of nature; but His Majesty was not learned in the laws of his realm of England, and causes which concern the life, or inheritance, or goods or fortunes of his subjects, are not to be decided by natural reason but by artificial reason and judgement of law, which law is an art which requires long study and experience, before that a man can attain to the cognizance of it.[6]

The printed script thus enabled royal absolutism, based on a rule by law (*rex lex loquens*), but in the end the proliferation of printed text provided the tools to resist absolute rule, creating the preconditions for the rule of law (*iudex lex loquens – le juge comme bouche de la loi*).[7] Moving from absolutism to a legally framed moderate government basically meant that law gained a measure of autonomy between ruler and subjects, providing the means to govern but also providing individual citizens with legal instruments to resist those in charge. Positive law attributes powers, turning them into legal competences and thus limiting their scope and exercise. This, again, is an affordance of the printed law, as it provides the room for interpretation and the

[6] Sir Edward Coke, conference between King James I and the Judges of England in 1608, 12 Coke's Reports 63, 65, 77 English Reports 1342, 1343 (King's Bench, 1608). Quoted by Posner (1990: 762).

[7] Montesquieu's famous adage is often understood as a reference to mechanical interpretation, but his point is more probably that the judge and not the king should interpret (speak) the law (cf. Schönfeld, 2008).

need for precise articulation of the protective as well as the instrumental dimensions of the law.

9.4. Law in a Smart World – The Collapse of Distance

9.4.1. Distantiation?

In acknowledging that modern law is a product of a particular epistemic shift made possible by a specific socio-technical infrastructure the question is raised what this means for law in a 'smart world'. How does the continuous availability of seemingly unlimited amounts of information and the subsequent need for scrutinizing, filtering and selecting affect your capability to seriously digest and analyze the knowledge it may contain? How does multitasking (like the combination of watching television, emailing, searching the web and checking social networking sites) affect your ability to reflect on the knowledge that is presented? How does hyperlinking from text to text affect the ability to sustain a carefully constructed line of thought? How do interactive websites where you click to get into the slots that raise your interest affect your attention span and your ability to focus? Evidently these questions can be addressed from a variety of perspectives but in this paper I am going to opt for one only. The question we face here is how digitalisation affects the fourfold distantiation described above.

9.4.2. The New Brain: Digital Natives, Immigrants; Net Geners and Boomers

To explore the effects of digitalisation on the distantiation that is typical for the era of the printing press, I will now present some of the findings of neuropsychologists and others who have investigated the cognitive styles of the generation that has grown up with the web. If the effects of the digitalisation are to be traced, this seems to be the right place to look for them. The idea that our current digitally mediated information and communication practices have an impact on the brain, has been put forward by neuropsychologists like, for instance, Gary Small. In his *iBrain. Surviving the technological alteration of the mind* he writes (Small and Vorgan, 2008: 77):

> Hyperactivity, inattention, depression, and multitasking mania are just a few of the behavioral consequences of the new techno-brain, though admitting that the science behind the way technology affects behavior and mental state is only in its infancy.

Small is especially worried about the lack of face to face communication that he thinks threatens the brains of those who replace direct interpersonal exchange with computerised interaction

(Small and Vorgan, 2008: 115-148). He warns that (Small and Vorgan, 2008: 73):

> with the digital age evolving our brains, some experts argue that our society in general is becoming more autistic.

Small even correlates this with an underdevelopment of the amygdala (an almond shaped part of the brain that integrates complex information from different parts of the brain, and that is found to be smaller in cases of autism). This is interesting as other researchers already found that the rate of people with mild forms of autism in the vicinity of Silicon Valley is extraordinary high, finding a correlation between autism, (computer) nerds and excellence in functions located in the right side of the brain (Raitey and Johnson, 1998). American scientist and industrial designer Temple Grandin (2000), wrote about her own autism under the title 'My Mind is a Web Browser: How People with Autism Think'. She writes

> I seem to lack a higher consciousness composed of abstract verbal thoughts that are merged with emotion.
> Grandin's type of autism means that she basically thinks in pictures, not in words. She explains how the language part of her brain and the "thinking in pictures" part seem to interact:
> My mind works just like an Internet Web browser. A Web browser finds specific words; by analogy, my mind looks for picture memories that are associated with a word. It can also go off on a tangent in the same way as a Web browser, because visual thinking is non-linear, associative thinking.

Autism connects to difficulties with abstract thought, as well as emotion. Abstract thinking requires a distantiation from ostensive reference, reaching out beyond the here and now, but still relating the abstract concepts to the concrete things they denote across different contexts. It is, however, one thing to find that autists have a problem with abstraction and are therefore attracted to working with computers, and quite another to suggest that working with computers could also lead to non-autist persons developing brains similar to those of autists. More research is needed to figure out to what extent and under what circumstances this can be confirmed (or falsified).

Whereas Small seems to focus on negative impacts others can hardly conceal their enthusiasm. Tapscott (2009) discusses a number of research findings about what he calls the Net Geners (Net Generation) or Digital Natives (cf. Prensky, 2001; Palfrey and Gasser, 2008). To give the reader a quick survey of the direction this research takes, I will provide some salient quotes. Tapscott notes (2009: 104) that

> boomers [the Baby Boom generation, or Digital Immigrants, MH] typically go from beginning to end – whether it's writing an essay, watching The Ed Sullivan Show, or reading the instructions before working the remote control. (...) The Net Gener doesn't operate in this sequential way. Using tools like keywords in Google, hypertext, and 'clicking, cutting, and pasting,' today's young person can search for and organize information containing links to other information.

He observes (2009: 105):

> It's as though their cognitive structures were parallel, not sequential[8]

referring to Marc Prensky's argument that

> 'this is one way that digital immersion has literally rewired brains under 40'.

Tapscott (2009: 108-9) cites Jordan Grafman, head of the cognitive neuroscience section at the National Institute of Neurological Disorders and Stroke (NINDS) as saying that

> the more you multitask, the less deliberative you become; the less you're able to think and reason out a problem and the more you're willing to rely on stereotypical solutions.

Tapscott nevertheless concludes that Net Geners are 'mentally agile' (2009: 118), and he describes the 'norms' (distinctive attitudinal and behavioural characteristics) that differentiate the Net Geners from their elders as freedom, customization, scrutiny, integrity, collaboration, entertainment, speed and innovation (Tapscott, 2009: 74).[9]

I don't think that it makes sense to discuss these distinctive characteristics in terms of good and bad compared with the 'norms' generated by the printing press. However, as these environments may introduce radical epistemic discontinuities that dissolve some of the affordances of the socio-technical infrastructure of the printing press, we should anticipate how this affects the legal framework of constitutional democracy. This framework presumes and produces citizens with a critical mind, capable of taking in lots of information without taking for granted anything that is written in print. The type of critical thought characteristically associated with printing press type of assessing information is based on a linear-sequential of reading information (starting on page 1 at the left top, moving from left to rights en from top down – sentence by sentence – and from page to page until the end of the book), and thrives on distancing oneself from

[8] Tapscott is citing William D. Winn, Director of the Learning Center at the University of Washington's Human Interface Technology Laboratory, from Prensky (2001).

[9] Tapscott devotes chapter 3 to elaborate on these 'norms' (Tapscott, 2009: 73-96).

whatever is presented while still following the line of thought throughout an entire article or book. Critical assessment is also a matter of taking distance in time, by incorporating delays and hesitations that allow time for chewing on the information provided, suspending one's judgement instead of assuming that one's first intuitions are generally right.[10] There is a healthy scepticism that seems to come naturally to the reading mind, having been confronted with opposite claims in print too often to be surprised. One may guess that Net Geners develop their own – different – form of scepticism. What Tapscott calls the 'scrutiny' of the Net Geners stands for their capacity to quickly detect unreliable information (spam, phishers, inaccuracies, hoaxes, scams, and misrepresentations) amidst the flood of bites that are competing for their attention (2009: 81). As they move ahead from click to click in search of interesting, entertaining or pertinent information, the overdose of noise does not merely make them sceptical but rather forces them to be alert, speedy and hungry for the right answer even before the question has crystallized – recognizing it when they bump into it, without going through the neat sequential process typical for the bookish mind.

We may conclude that there is a kind of parallel processing that seems intrinsic to the mind of frequent web-users, differing radically from the linear-sequential mind of those immersed in the culture of the book. At the level of the brain there seems a shift from left to right hemisphere thinking. How must we understand this epistemic of parallel processing in relation to the distance inherent in the epistemic of linear, narrative or argumentative discourse?

9.4.3. Distantiation and Virtualisation

In his magnificent description of what he calls 'technologies of intelligence' cyberphilosopher Pierre Levy (1990) traces the epistemic shifts from orality through script and printing press to the present era of the digital. Instead of speaking of *distantiations* he discusses the process of disentanglement of the text from its intended meaning, from the author, from its ostensive reference, and from a restricted audience in terms of *virtualisation*. He thereby integrates a vocabulary introduced by Deleuze, who differentiated between the possible and the real on the one hand and the virtual and the actual on the other. The possible is not real but it does not leave any room for creative application: becoming real is a matter of mechanical application. A computer program that executes itself renders manifest what was

[10] About hesitation as a crucial characteristic of the 'régime de veridiction' of the law, see Latour (2004). See the English translation of chapter 5 at http://www.bruno-latour.fr/articles/article/088.html. (accessed 26 February 2010).

possible, its application is real but does not bring anything new that was not determined in its design. The virtual, however, is already real, only not manifest: becoming actual is a process informed by constraints but not fully determined, requiring the invention of creative solutions to intervening problems. The seed of an oak tree may start growing if the circumstances are favourable, and though we can be sure that it will not become manifest as a birch or a chimpanzee we cannot predict what kind of oak tree it will become. This will depend on the interplay between the seed and affordances of the environment at a specific point in time and space.

Curiously, Lévy is more interested in the reverse process: moving from actualisation back to the virtual, which he defines as articulating the question to which an actualisation was an answer, or, situating the problem to which an actualisation was a solution. By reverting back to the question, room is created for other answers and by locating the problem, the scope for other solutions becomes visible. Understood in this sense, virtualisation is a matter of distantiation from the actual: from the actual meaning of the text as it was intended, from the actual author of a text, from the ostensive reference to an actual *Umwelt*, from an actual audience. As Lévy claims in other work (1998), language, money and contracts are all examples of virtualisation, broadening the scope for new and different actualisations by those who engage in or with them.

At first sight digitalisation simply explodes the distantiation or virtualisation described so far. This explains Lévy's enthusiasm for the digital age: it affords an unprecedented acceleration of the process of virtualisation, providing the possibility to break down reality into bits and pieces that can be stored as digital data, mined and recombined to form new information and unexpected knowledge constructs which can be actualised as new answers and different solutions to whatever problems we face. A perpetual process of de-contextualisation and de-territorialisation is followed by re-contextualisation and re-territorialisation, which – in the flux of a moment – can be deconstructed all over again into novel machine-readable bits and pieces. The result of all these instantaneous permutations and combinations (Kallinnikos, 2006) is a transition from a linear sense of time to segments and points, from accumulation of texts to instant access to texts, images and sounds (sampled and recombined), from delay and duration to real time and immediacy, from universalisation inherent in the printed script to recurring contextualisation, from theory to modelling, from interpretation to simulation, from semantics to

syntax and pragmatics, from truth to effectiveness and from stability to change (Lévy, 1990).[11]

What strikes me here, however, is that at some point the discourse moves away from distantiation to a kind of instantaneous integration of what *was*, *is* and is predicted to *be* as well as of the *here* with any kind of *out there*. It seems as if synchrony and diachrony collapse into each other due to an implosion rather than an explosion of distance. The virtual seems to become the first modality of the real, taking the place of the actual, or somehow conflating with it. It is tempting to celebrate this virtualisation-run-amok as an ultimate freedom from the constraints of the actual, but there are some drawbacks here.

9.4.4. Implosion of Distantiation

In an as yet unpublished paper, philosopher of technology Don Ihde saliently refers to this implosion when he describes the experience of what he calls 'Einsteinian time' 'where space-time displays both its spatially distant, temporally located structure'.[12] His description concerns his email communications with a Japanese host at a time difference of 12 hours, confronting him with a sense of 'the *materiality* of temporality'. Interestingly he adds that

> clearly such a space-time is neither *linear* nor *universally uniform* time.

It is hard to articulate what differentiates this sense of space-time from our common sense experience of space and time as separate 'Formen der Anschauung' (Kant) that have a linear structure supposedly hardwired into the brains. The difficulty of articulating space-time may reside in this hardwiring, making it hard to escape the linearity of reasoning. It could be, however, that the difficulty is connected to the specific cognitive capacities developed in the era of the printing press. Writing down one's argument induces (if not enforces) linear thinking. If the left hemisphere is where pattern recognition is sedimented

[11] On the idea that modern law is basically geared to the conservation of continuity, see Katsh (1995a); less conventional, see Glenn (2004) on the profound insight that modern law has incorporated the idea and the possibility of explicit change, precisely because changes can be recorded in writing and print. Interestingly both authors discuss law in terms of information, though coming from very different angles. Lévy's (1992) analysis goes much further than that of a mere acceleration of change. He seems to have grasped the partial conflation of time and space generated by web 2.0 technologies and the move from what Manovich (1998) called a shifting emphasis from narrative to database, well in advance of the widespread use of groupware and smart technologies.

[12] The paper 'IT: Clouds and Cyberspace-Time' was presented at the colloquium on 'The Impact of Autonomic Computing on Human Identity and Legal Subjectivity' held on 16 January 2009 in Brussels, as part of the Conference on Computer, Privacy and Data Protection 2009 (CPDP2009). To be published as a chapter in Ihde (forthcoming 2010).

(Goldberg, 2006) we may guess that the practice of reading and writing hardwires us for linear thinking. This would entail a potential transformation of our perception of time-space due to the affordances of digital infrastructures. Increased virtualisation seems to coincide here with reduced distantiation. The culmination of the virtual, coupled with the implosion of distance allows one the experience of both oneself and the world in an extended here-there and now-then, which become entangled into an extended here-there-now-then. One comes to ride a wave of speed, scrutiny and simultaneity that could radically alters one's perception of self and other, let alone one's conception of 'things' like privacy, fairness, non-discrimination, due process, equal treatment and the like. Concepts like privacy, due process and fair treatment all depend on a practice of distantiation, which sounds like an anachronism in the conflated virtual-actual worlds that we are on the verge of entering. Indeed such conflation is already visible in the interpenetration of the private and the public.

The loss of distantiation could in fact trigger the end of law as we take it for granted today, generating other cybernetic technologies, geared more adequately to *an offline world turned online* (web 3.0).

9.5. Regaining Control – Distantiation in the Era of Real Time Profiling

9.5.1. Real Time Profiling and the Loss of Interpretation

If written (printed) law was an important cybernetic technique that afforded (made possible) not only an extended sovereign rule by law, but also the moderate government constraint by the rule of law, we need to urgently assess how new cybernetic techniques interfere with, complement or reinforce the rule of law. Modern law has enabled citizens to contest dominant frames of interpretation imposed by governmental agencies, commercial enterprise or public opinion. This has afforded citizens a relative control over how their behaviours are categorized and qualified. Rights like that to privacy and data protection, as well as non-discrimination and due process restrict the extent to which citizens are determined by the interpretations of others, allowing them to resist stereotyping and normalisation.[13] Law has a subversive dimension that crucially depends on the fact that any interpretation can – at some point – be contested, due to the ambiguity produced by the distantiation that is inherent in language, reinforced by the script and the printing press. Can the law provide citizens with novel legal instruments to regain such relative control against the

[13] See also Stalder (2002), who discusses privacy as an affordance of the printing press, emphasizing the advent of silent – private – reading as a consequence of the proliferation of books.

statistically inferred interpretations of profiling machines operating in search machines (Amazon.com), social networks (Facebook), online gaming (World of Warcraft) or virtual worlds (Second Life)? Could it be that the introduction of novel cybernetic techniques, based on real time autonomic proactive computing implode the distance between author, text and reader to such an extent that interpretation becomes invisible and indistinguishable from perception and action? In the heading of this section I refer to this as a loss of interpretation. The reader may counter that what I intend to discuss is the loss of conscious awareness of the fact that interpretations are being made. This fits the linear-sequential logic of the era of the book: it presumes the distantiations that provoked the need for interpretation. From the perspective of parallel processing the concept of interpretation needs clarification. Concepts like simulation and dynamic modelling fit better with the synchronisation of events that take place at different places and at different points in time. It may be that what is loss of the conscious awareness of interpretation from a hermeneutical, textually saturated perspective, is simply a loss of interpretation from the perspective of real time parallel processing.[14]

9.5.2. The Contestation of Real Time Interceptions

The implosion of the distantiations discussed above creates what I would like to call 'real time interception'. In technical terms 'real time' is defined as referring to 'sensing and responding to external events nearly simultaneously (e.g., within milliseconds or microseconds) with their occurrence. It is employed mostly in systems in which the results of the computation are used to influence a process while it is occurring'.[15] In much discourse about the internet, social networking, autonomic computing and AmI, 'real time' stands for the fact that communications originating from events that are dispersed in time and/or space coincide on the computer screen where they are also continuously updated. This update not only concerns events the user might be interested in, but also the profile of the 'user' who is assessing the screen. Based on machine profiling that involves real time matching between 'available machine readable events' and the inferred preferences of the user, every single user is confronted with a different screen (Sunstein, 2001). The online environment is not only

[14] The implosion of distance and the related move from linear sequential thinking to parallel processing can be connected with a shift from narrative coherence to 'database' coherence, see Manovich (1998).

[15] Cf. the Linux website at http://www.linfo.org/real_time.html. (accessed 26 February 2010). They contrast with: 'time shifting, which is the situation in which a system responds to external events at its convenience or in batches.'

interactive, but tries to stay one step ahead of the user, proactively catering to her inferred informational needs and personal desires. Since amazon.com, we realise that the inference of our needs and desires are not based merely on our own past behaviour but on statistical correlations with a mass of other data. Real time updating of your amazon.com profile is not restricted to updates in relation to your own shopping behaviour, but consists of a continuous update of inferred group profiles (based on the shopping behaviour of the mass of amazon.com users) and may also relate to your clicking behaviours (checking which books you 'visit' without buying them). With 'interception', I refer to the fact that one is continuously 'leaking' information that is intercepted, stored, aggregated and mined by profiling machines. This seamless, invisible interception of seemingly trivial behaviour, like biometric (e.g., keystroke), surfing (which types of websites do you visit) or transactional (online buying) behaviours, allows for real time application of profiles. In a way your own behaviours – correlated with those of others – are fed back to you, qualifying you as 'that kind of person', who 'prefers this kind of furniture', has 'that type of friends', reading 'a specific range of journals of newspapers', correlating with 'such an earning capacity' or with 'this particular credit-risk'.

The simultaneity that is implied in real time interception generates a continuity of synchronised machine interpretations. Due to the flux of the real time interception these interpretations are adapted even before we had time to consider them as interpretations. As Tapscott contends, the scrutiny of the digital native allows her to ride the wave of real time interceptions, providing her with an acute sense of control. One could counter, however, that she is the floating object of highly sophisticated machine manipulations that have no author in the traditional sense of the word, but that still direct her behaviours in a powerful way that can best be described as subliminal.

9.5.3. Regaining Control?

Now, let's get back to the question of how the law can help this floating object to regain some form of control. How can a person contest or resist the way she is being profiled if the process of profiling is both invisible and in such flux that by the time you have access to a profile that concerns you has already been replaced ten times by newly attuned profiles? In other work I have looked into the issue of transparency, or rather the lack of it (Hildebrandt and Meints, 2006; Hildebrandt and Koops, 2007; Hildebrandt, 2008; 2009). Here I will try to assess the challenge of the *speed* inherent in real time interceptions for the present legal framework. My fear is that as modern law is based on the

distantiation, hesitation and delay that is typical for the bookish mind, it may fail to provide solace for those whose brains nourish on parallel processing. They may be merely irritated with the hesitation and delay afforded by the distantiations of the (printed) script, and opt for a default that skips such irritations. As noted above, the increased capacity of digital natives to process different types of information at the same time (multitasking) while instantly detecting what is reliable information amidst the noise (scrutiny) does not correlate with an increased capacity for critical thinking. The scepticism of the bookish mind is not equivalent with the scepticism of the online interconnected hyperlinked mind of the digital native. To regain the type of control that is based on bypassing one's immediate reflexes in order to critically assess the content one is presented with and in order to critically assess the profiles that determine how one is treated we may need to design some delays into the socio-technical infrastructures.

In other work, focusing on transparency issues, we have discussed the need for Ambient Law (AmLaw). The idea is that using written law to regulate the digitally interconnected environments (presently online, if AmI manifests itself also in the offline world turned online), is an inadequate undertaking, doomed to produce more ineffective legal protections that can be used to legitimise further encroachment on privacy and non-discrimination but hardly deliver the effective remedy we need (Hildebrandt and Koops, 2007; Hildebrandt, 2008). AmLaw would articulate legal transparency tools into the technical infrastructure, providing citizens with a reliable hunch of how they are being profiled by whom and which could be the consequences (Hildebrandt, 2009). The idea of using technologies – instead of legal rules – as instruments to regulate human behaviour, is nothing very new. Lessig (1999) has argued that computer code is indeed regulative – if not constitutive – of society to an extent many legal scholars do not acknowledge. His point is that if we want to retain our constitutional safeguards we need to think hard about how to design the communication infrastructure in ways that afford 'fair use' of copyrighted materials and provide an incentive to preserve privacy with regard to digital personal information.[16] Similarly Thaler and Sunstein (2008) have recently indicated how simple default settings in our physical and virtual worlds can 'nudge' us into desirable behaviours.

[16] Building on insights of law and economics he proposes the commodification of personal information, thus creating a market that should empower users by giving them a measure of control over their personal data. Taking Lessig's point seriously, Schwartz (2000) has convincingly refuted the idea that commodification would create a fair market, because of the immense knowledge asymmetry between those leaking personal data and those mining them. Transaction costs will induce a market failure.

Though the recognition that technologies have a normative impact on human behaviour is a laudable step forward (Hildebrandt, 2008), especially for lawyers that seem overly focused on the use of written – enacted – texts to coordinate interaction, other legal scholars (Brownsword, Tien, Reidenberg) have rightly warned against the pitfalls of what could end up as a rule of technology instead of a rule of law (Hildebrandt, 2009). AmLaw does not advocate the use of technological *instead of* legal instruments, which would imply an instrumentalist conception of both law and technology. First, AmLaw acknowledges that law is already technologically embodied in the technology of the script. Second, AmLaw suggests articulating */legal/* norms into the technological infrastructure we need to protect against. By emphasizing that it is */legal/* norms that must be articulated in the novel communication technologies, the requirements of legal regulation in a constitutional democracy must be heeded: the enactment of these norms must be initiated by the democratic legislator and/or the courts and their application in concrete cases must be made contestable in a court of law. These two constitutive features of democratic government and the rule of law prevent the use of technology instead of law: AmLaw is not merely a matter of implementing written law by means of effective technologies, thus forcing citizens into compliance. That would indeed be the end of the rule of law. The legislator will have to sit down with computer scientists and experts in constructive technology assessment (Rip, 1995) and human computer interfaces (Suchman, 2006) to co-design the affordances of the novel infrastructures, taking care that whatever defaults are set in place citizens must have effective means to contest the application of legal rules as unjust, unfair or as an invasion of their privacy not necessary in a democratic society (art. 8 (2) of the European Convention of Human Rights).

As mentioned above, we have worked on AmLaw as a way to attribute technologically embodied transparency rights with regard to profiling technologies (Hildebrandt, 2009). This is a formidable challenge, because most transparency enhancing technologies (TETs) are focused on personal data instead of the profiles with which these data match. Even so, transparency will not solve the issue of speed and the concurrent collapse of distance that seems a more profound epistemic shift of which the lack of transparency may be a mere symptom. Indeed transparency won't solve the problem if it means providing users with lengthy details about algorithms or lots of text explaining how they are being profiled. Digital natives will probably find this utterly boring content that takes attention away from what they consider pertinent. If we want to sustain the distantiation that is critical

for issues like privacy, due process and non-discrimination, we will have to figure out how this distantiation can be built into the emerging infrastructure without destroying the many advantages it brings. The point will be to retain the increased virtualisation while reinstalling the distantiations that allow for a deeper scrutiny. The question is whether this is possible: to have our cake and eat it too.

9.6. Concluding Remarks

So far, law has been articulated in the technologies of the script and the printing press. This has afforded an epistemic shift entailing a fourfold distantiation: of the meaning of a text, of its author, of ostensive reference and of its public. This distantiation has turned the law into an effective cybernetic technique, if we understand cybernetics as 'control at a distance'. At the same time, it has turned the law into an instrument of protection, because of the need for interpretation generated by the distance between author and reader of the law (legislator and subject), thus also triggering the advent of a relative autonomy of the law. Legal protections like the right to privacy and non-discrimination as well as due process fit the epistemic of hesitation and delay, enabling reflection, autonomy and contestation.

The digitally mediated mind of a new generation, called digital natives or net geners, is no longer geared to the linear-sequential cognitive style of the bookish mind. Instead of starting to read at the left-top part of a page and slowly and steadily moving from left to right, from top to bottom and from page to subsequent page, the digital native practices parallel processing and multitasking, keeping an eye on everything and clicking on whatever appears to be pertinent. The speed and immediate perceptive skills of digital natives contrast with the careful step-for-step intake of information of digital immigrants: the scrutiny of the net gener seems of a different kind compared to the critical mind of the prototype of the bookish mind: the learned scholar.

The shift from printing press cognitive structures to real time parallel processing seems to involve the collapse of the distantiation inherent in the previous socio-technical infrastructure. Though we can expect both infrastructures to co-exist (the script has not entirely disappeared with the advent of the printing press – though it may still disappear with the advance of the keyboard and the computer screen) the impact of real time communication and interaction between humans and machines will have a profound impact on how we perceive and interpret our environments. The problem that I have tried to outline in this paper is that the implosion of distance could jeopardize our ability to critically assess the way our environments communicate

and interact with us. Immediacy and instant pertinence cannot replace reflective thinking, needed to acknowledge that and how our behaviour is being interpreted (for instance, by profiling machines).

The challenge for the law is to rethink its technological articulation. To sustain the distantiation inherent in modern law legal protection will need to be rearticulated into the digital infrastructures that will soon regulate our daily life, our critical infrastructures, our educational and professional settings, healthcare, defence etc. To ensure the distance needed for hesitation and contestation as preconditions for the legal protection of privacy, non-discrimination and due process this distance will have to be introduced into the emerging smart, real time environments. To succeed, the distance will have to be a constitutive part of the smart infrastructure, without losing the thread between law and the digitally native citizens it aims to protect. As discussed in other work, designing legal protection into the Ambient Intelligent environment (Ambient Law) will require creative cooperation between lawyers, legislators, computer scientists and citizens. This paper is merely an attempt to focus on what is at stake.

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Chapter 10. Pervasive Science. Challenges of Contemporary Technosciences for Governance and Self-Management

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Abstract
According to Hegel, the basic assignment of philosophy is to capture the present in thoughts. When it comes to understanding our present, an assessment of the technosciences and their impact on our view on nature, society and ourselves must be of key importance. A prominent feature of contemporary technosciences resides in their pervasiveness: the extent to which they pervade nature, society and human bodies, even on a molecular level, as well as each other. On the one hand, the 20th century is the era of the elementary particles, of identifying the elementary subatomic and molecular building blocks of matter and life. On the other hand, it is the era of complexity, of evolving systems. In both directions, our understanding of ourselves is challenged and deepened by technoscientific explorations. Increasingly, moreover, our technologies tend to become nature-like. This allows us to embed them more adequately in natural systems, but it also opens up unprecedented opportunities for modifying natural systems, including human bodies. How are we to address the bioethical and biopolitical prospects and concerns implied in these developments?

10.1. Introduction: Assessing the Present and Exploring the Future: the Basic Assignment of Philosophy

Das was ist zu begreifen, ist die Aufgabe der Philosophie (...)
[Sie ist] ihre Zeit in Gedanken erfasst
(Georg Wilhelm Friedrich Hegel)[1]

According to Hegel, the basic "assignment" of philosophy is to assess the present, to capture it in thoughts. When it comes to understanding *our* present (i.e. the contemporary world), science and technology, including their impact on contemporary knowledge societies, must evidently constitute a major target of reflection. Is it still possible, by way of a "Hegelian" effort, to capture the basic profile of the contemporary sciences in a single term? Such an effort would constitute a starting point for a systematic exploration of the future, while such an exploration in its turn would provide us with input on how to address the bioethical and biopolitical challenges of the present. In the

[1] Hegel (1821/1970), p. 26.

following section, I will outline the idea that a rather prominent feature of the contemporary technosciences resides in their pervasiveness, the extent to which they are effectively pervading, and being pervaded by, each other, as well as by their scientific and social environments in various ways. They not only deepen and broaden our understanding of the world and of ourselves (section 3), but also produce new "biomimetic" technologies that allow us to interact with natural systems, both "internally" (inside our bodies) and "externally" (outside our bodies), in more intimate and effective ways, opening up prospects for modification that are as fascinating as they are uncanny.

10.2. Pervasive Science

We are surrounded and embraced by her: powerless to separate ourselves from her, and powerless to penetrate beyond her (...). She is ever shaping new forms: what is, has never yet been, everything is new, and yet nought but the old. We live in her midst but know her not. She is incessantly speaking to us, but betrays not her secret. We constantly act upon her, and yet have no power over her (...).

These are the opening lines of the first issue of the journal *Nature*, published in 1869 and written by Thomas Huxley. Actually, these lines were borrowed from Goethe's famous fragment *Die Natur*. The basic idea of this paper is that what Goethe has written so eloquently about nature can now be written about the contemporary technosciences using the very same terms: we are surrounded by them, powerless to separate ourselves from them, we constantly act upon them, yet have no power over them.

Thus, I take pervasiveness to be a key feature of the emerging technosciences. They pervade natural systems in various dimensions, from the immensities of the galaxy down to the nanoworld of elementary particles and the basic molecular structures of biomaterials and living systems. Moreover, technosciences are pervading the bio-worlds of ecosystems and ecological networks, opening up unexplored realms of microbial life. But they also pervade us: our bodies and minds. Building on techniques ranging from genomics to brain imaging, they are analysing the dynamics of cognitive and emotional functions in a much more detailed way than ever before. Technosciences (ICT, genomics, nanoscience) are permeating everyday life, becoming ubiquitous, embedded and highly adaptive.

Technosciences also pervade *each other*. Disciplinary compartmentalisations give way to emerging supra-disciplinary fields, involving experts from a broad range of disciplines in large-scale research programmes. Traditional distinctions (science vs. technology, funda-

mental vs. applied research, nature vs. technology, subject vs. object) are increasingly difficult to uphold. Finally, emerging technosciences pervade and *are pervaded* by society in far-researching ways. They permeate the ways in which we communicate and interact with one another, significantly affecting social change in knowledge societies. At the same time, societal dynamics have a profound impact on the ways in which research is organised and research agendas evolve. Pervasiveness inspires both fascination and concern.

Although the societal import of pervasiveness will eventually present itself in terms of concrete and acute bioethical issues, the assessment of these issues must build on a thorough analysis of the manner in which new scientific insights and approaches actually "inform" society, notably by affecting the way we see ourselves, i.e. the way in which we assess our contemporary being-in-the-world. This is done in two directions: firstly by deepening (on the molecular level) the molecular and genetic basis of our functioning as human beings; and secondly, by broadening (on the ecological level) our self-awareness of our embedding within complex and dynamical external networks. Thus, novel scientific approaches significantly influence the manner in which we assess our own functioning. Rather than expanding our knowledge of ourselves as human beings in an *anthropocentric* fashion, in isolation from the rest of the biosphere, our functioning is now explored and assessed against the backdrop of the internal and external networks that allow us to exist and are affected by our policies and behaviours, as individuals and as societies. Self-knowledge as such is not the endpoint of our desire to know. On the contrary, as has been articulated by Nietzsche, Foucault and others, the will to know (ourselves) is inspired by a will to transform, to control and to improve (ourselves). In terms of our ecological functioning, new scientific insights may provide opportunities for more sustainable forms of interaction and co-development, but also for strengthening our technological sway of nature in more sophisticated and effective ways. In terms of physical and cognitive functioning, new scientific insights may provide opportunities for performance enhancement. Yet, in order to realize these opportunities, natural systems (including our own bodies) will be permeated by our probing and our modifications, and this process is bound to entail a plethora of (often unprecedented) bio-ethical quandaries. Although on the *conceptual* level the distinction between "Self" versus "nature" and between *understanding* nature (or ourselves) and *manipulating* nature (or ourselves) may be clear, in actual practice, in the context of emerging technosciences, these processes are often implicated in one another, so that manipulation enables us to further our understanding, while a refined and sensitive understanding

may allow us to manipulate natural systems or human bodies in more effective ways. How should we assess these newly emerging avenues and opportunities for modification and self-modification? Before addressing the quandaries involved in bioethical and biopolitical terms, a thorough analysis of the type of knowledge involved is called for.

Regardless of whether this analysis is directed towards the micro-level of molecular functioning or towards the macro-level of ecological functioning, in both cases our will to know is inspired by the idea that novel technosciences may allow us to develop new generations of nature-like (bio-mimetic) technologies that may enable us to interact more directly and intimately with natural systems and processes, including ourselves. This is a perspective that provokes both fascination and unease. In the next sections, two core aspects of pervasiveness will be explored more thoroughly. On the one hand the relationship between pervasiveness and the Self (pervasive Self-understanding) – or rather: the blurring of the boundaries between technology and the Self – and on the other hand the relationship between pervasiveness and nature – or rather: the blurring of the boundaries between pervasive technologies and natural systems, represented by the emerging possibilities for biomimesis and biomimetic interventions.

Scientific research takes place in the context of a triangular relationship involving three "poles" that mutually imply and affect one another, namely the pole of *knowledge* or *science* (the technosciences), the pole of *nature* (natural systems) and finally the *human pole*, the pole of the Self (of individuals, communities and societies). None of these poles can be meaningfully studied in isolation from the others. Nonetheless, in the context of philosophical research activities, the focus of attention may temporarily shift from science, to nature, to Self and vice versa.

10.3. Pervasiveness and Self-knowledge

> *"Know then thyself, presume not God to scan,*
> *The proper study of mankind is man"*
> (Alexander Pope, Essay on Man)[2]

Having identified pervasiveness as a key feature of contemporary research activities, the "second step" in the argument begins from the observation that the ultimate target of the pervasive research under

[2] Cited at the Press Conference (26 June 2000) announcing the impending completing of the human genome sequencing effort (Zwart, 2008).

study apparently resides in understanding, improving and managing human life itself. Thus, the outcomes of pervasive research are bound to significantly affect the ways in which we come to see, and subsequently to develop and manage ourselves. It is indeed astonishing that, regardless of the disciplinary backgrounds of the research communities involved – (bio)physics, (bio)chemistry, (bio)informatics, the molecular life sciences, etc. – they eventually are bound to contribute to the converging ambition of elucidating the functioning of ourselves as human beings. This is not to suggest that contemporary technosciences are *anthropocentric* in their basic orientation; rather the contrary is true. Paradoxically, although pervasive research entails important messages for self-understanding, it eventually undermines rather than strengthens an anthropocentric understanding of ourselves. Through pervasive research we deepen and broaden our self-understanding in the sense that we become increasingly aware of the entanglement of our functioning within the webs and networks of life on all levels. In order to understand ourselves, pervasiveness allows and incites us to focus on understanding our relatedness with other species as well as with a broad variety of natural systems.

This "gathering" of research communities around the analysis of human life itself, is the outcome of a longer history. Whereas the first half of the 20th century is generally regarded as the Golden Age of modern physics, resulting in groundbreaking "applications" such as nuclear energy and the atomic bomb, most of which involved major and unprecedented ethical and biopolitical challenges, during the second half of the 20th century, the focus of the scientific revolution that began in 1900 (with the introduction of the quantum-concept, the mutation-concept, the rediscovery of Mendel, etc.) shifted towards the biofields, notably affecting the research practices that centred on elucidating human functioning. It is indeed astonishing that disciplines such as physics, chemistry, informatics etc. gradually shifted their focus of attention and by and large transformed themselves into biophysics, biochemistry, bioinformatics and the like. An important signal for this migration trend was the publication in 1944 by the prominent physicist Erwin Schrödinger of the scientific best-seller, *What is life?*, in which he urged physicists to turn attention to the elementary particles of life. The book coincided with the Manhattan Project and greatly influenced a whole cohort of physicists (Delbrück, Wilkins, Franklin, Crick, Collins, etc.) in migrating towards biofields – a development that has had a significant impact on methodologies, technologies and mind-sets of life-science researchers. The discovery of the structure of DNA in 1953 by a biologist and a physicist, building on physical and chemical

technologies and methods such as crystallography and molecular model-building, symbolised this trend. And physics brought with it the use of large equipment and, eventually, of big science. Indeed, an important aspect of the transformations currently evolving in research are the remarkable increase of pace and scale as well as the role of high-tech equipment, notably ICT. Eventually, these variously evolving disciplines will begin to address some of the unexplored domains of human life, notably on the molecular and ecological level, such as our "internal" and "external" (genetic, molecular, neural, ecological, etc.) networks, thereby significantly challenging and affecting the way we look upon ourselves.

Elsewhere (2007) I have outlines how genomics has fuelled and revivified fundamental debates concerning our ambition to know ourselves. (Bio)physics, (bio)chemistry, (bio)informatics and a plethora of other emerging research practices increasingly focus on elucidating human behaviour and human functioning on all levels (genetic, physiological, cognitive, behavioural) and in various dimensions. Firstly, by focusing on the extremely small, the study of life "from molecule to man". Thus, the analysis of our internal networks and pathways has become a converging field involving a broad range of experts from various scientific backgrounds (ranging from mathematics and physics up to the human sciences and humanities). Secondly, contemporary research practices are deepening our understanding of our embeddedness in socio-cultural and symbolical networks that greatly affect our cognitive functioning. Human intelligence is not only a result of our having a well-developed brain, but also the fact that our cultural and symbolical environment *facilitates* intelligent behaviour. In other words, our intelligence is the outcome of a complex interaction between our neural networks on the one hand and our symbolical systems and networks (verbal communication, writing, mathematics, politics, ethics, etc.) on the other. Thirdly, we have become increasingly aware of our intimate entanglement in broader networks and webs of life in various ways (the analysis of our external biological networks). We increasingly see ourselves as elements in ecological networks whose "health" and functioning is greatly dependent on our decisions, policies and behaviour. Moreover, we increasingly see ourselves as "super-organisms", as containers hosting a plethora of microbial life forms, on whose "labour" the greater part of our metabolism depends. Finally, we increasingly see ourselves as the outcome of a history that must be interpreted as a narrative of evolving ecological networks rather than as a single-species (anthropocentric) story (Jones, 2001). Our history is basically a multi-species history, a co-evolution of human beings and

various other species whose vicissitudes are intimately intertwined with ours, a story of interactions between human communities, domesticated animals, cultivated plants and modified environments. In other words, our understanding of ourselves is both deepened (on the molecular level) and broadened (on the socio-cultural level) and widened (on the ecological level). This increased Self-awareness opens up new challenges and possibilities for self-management (bioethics) and governance (biopolitics).

Self-knowledge is not an end in itself, in terms of the cognitive insights it provides, but also a precondition for managing and even improving ourselves: our functioning as well as our societal and ecological embedding. And pervasive research furthers this process not only by enriching our understanding, but simultaneously by providing new tools and technologies that may allow us to *use* these insights for governance (biopolitics) and self-management (empowerment). Notably, pervasiveness gives rise to a plethora of bio-mimetic technologies that can *in theory* be applied to manage and improve, in a "nature friendly" manner, both our own physiological, senso-motorial and cognitive functioning as well as the functioning of the ecosystems we inhabit.

10.4. Biomimesis as a Key Aspect of Pervasiveness

> *Gardeners now use DNA kits (...). People are making genetically modified roses all over the world (...). The technology is everywhere*
> (Michael Crichton, *Next*)

An important characteristic of emerging technosciences, and an important aspect of their pervasiveness, is their tendency to see themselves as much more "natural" (more adaptive to nature) than previous forms of human technology. Novel technosciences claim to be increasingly able not only to permeate and explore but also to mimic and imitate the technologies nature herself has produced in the course of billions of years of evolution. Ever since its introduction during the late 1990's, the concept of biomimesis (or biomimetics) has become popular in a number of research fields, such as material science (Mann, 1997; Bensaude-Vincent, 2002) and has made its appearance in top journals such as *Nature* (Ball, 2001; Sanchez et al., 2005). According to Sanchez, for instance, biomimesis is "one of the most promising scientific and technological challenges of the coming years" (2005: 285). But what exactly is biomimesis?

Biomimesis refers to the objective of reinserting artificial (man-made) systems in natural systems in such a way that the artificial

system becomes optimally embedded. The idea is that natural systems and materials display a high degree of sophistication and adaptability and that nature, in the course of evolution, has generated a plethora of techniques (solutions to functional problems of living systems) that can be studied and imitated by contemporary technoscience. The ultimate goal is to reintegrate the technosphere into the biosphere (mutual pervasiveness of technology and nature). Whereas in the past the focus was on using technology to *improve* nature, nature's "pool of ideas" now increasingly becomes a source of innovation and improvement for molecular technology (Ball, 2001). Notably, the wasteful systems of human production might be replaced by the more cyclical and sustainable economies characteristic of natural systems. Indeed, the idea of biomimesis is closely linked to that of sustainability. Although the concept as such has a long history in aesthetics and architecture – in its present form it was introduced by Warren McCulloch in 1962 – it became a key term among life scientists only from the 1990s onwards.

In the past, a "Faustian" view of the relationship between science and nature was regarded as dominant. Science and technology were seen by their protagonists as instruments for gaining mastery over nature. The Faustian will to know gradually forced its way down to the basic and elementary building blocks of nature, as was articulated by Goethe in his famous lines from Faust, cited, for instance, in the novel *Elementary particles* by Michel Houellebecq (1998): *Dass ich erkenne, was die Welt / Im Innersten zusammenhält*. Yet, notwithstanding the Faustian desire to intimately explore the secrets of nature, the basic Faustian drive has always been to use this knowledge in order to go *beyond* nature, to transcend and improve nature. This is the basic Faustian ambition: from creating artificial human life in the laboratory (the homunculus scene in *Faust*) up to creating an artificial manmade landscape as a technological "paradise" (the polder scene in Faust).

This Faustian ideal also applies to "classical" biotechnology. Around 1900, biologist Jacques Loeb (1859-1924) voiced the idea that nature must be regarded as raw material, to be modified and improved by bioengineers (Pauly, 1987). Biology's core objective, Loeb said, is the improvement of nature. Why accept existing biological constraints as given? Why not use biological knowledge in order to improve life and – eventually – ourselves, much more directly and effectively than we have done so far? Why not prolong the human life-span or opt for artificial instead of sexual reproduction? Indeed, the famous first chapter of Aldous Huxley's *Brave new world*, describing the "Central London Hatchery and Conditioning Centre", consciously echoes Loeb's ideas. The first chapter describes how the chemical environments of embryos

kept in vitro are systematically manipulated in order to adapt them to societal demands and actually contains references to Loeb's views.

Thus, the Faustian ambition has been to use our knowledge concerning the building blocks of nature in order to transcend natural limits and to move human life into new, "postnatural", directions. This is also the case in relation to the biotechnological revolution that emerged during the final decades of the twentieth century. Genes could now be deleted or inserted in order to transcend natural borders and boundaries (such as between species) and to produce new life forms. Thus, nature was the target, rather than the model, and the orientation of biotechnology was trans-natural. The bioengineer was the active agent who actively aimed at modifying nature. Through science and technology, landscapes could be cultivated and plants and animals could be adapted to human interests, either through genetic modification or otherwise.

Newly emerging pervasive technosciences, however, increasingly claim to incorporate a different vision of nature. It has become an important objective and promise of pervasive science to facilitate the emergence of new generations of nature-friendly and environment-respecting technologies that may allow us to interact with nature in a much more sustainable, fine-tuned and sensitive manner. The basic idea is that by permeating natural systems more intimately than ever before, technologies can now be designed that mimic and build on the "technologies" developed by nature herself, in a more refined fashion, allowing us to use the potentials and resources of nature (described as "Ali-Baba's cave of technology", Sanchez et al., 2005) in more intelligent and considerate ways.

Yet, of course, the new pervading technosciences may also be seen as pathways towards mastering and manipulating nature more effectively than ever before; our age is arguably becoming more Faustian than any previous century. An even more sophisticated will to power may, in a cunning manner, have appropriated the rhetoric of biomimesis and sustainability. Thus, in addition to a seismographic sensitivity for what is happening in contemporary research, contemporary philosophers of technology and science should maintain a healthy attitude of suspicion.

Nonetheless, the concept of biomimesis deserves to be taken seriously. In a much-cited review article, Viola Vogel (2002) addresses this development under the heading of "reverse engineering": the basic effort to reorient the innovation process, taking molecular nature as the model. Her focus is on proteins: nature's "workhorses". According to Vogel, a fine-grained understanding of the underlying design principles that allowed proteins to evolve and to fulfil a plethora of functions can

provide researchers with new insights into how to enhance the performance of synthetic artificial systems with increased sophistication. For example, proteins can specifically recognize other biomolecules with a selectivity and affinity several orders of magnitude superior to their synthetic counterparts, which offers prospects for biomimetic biodetection. Proteins can also be used as switches in artificial systems or as micro energy convertors or producers. A plethora of lessons can be learned from how nature solves the challenge of functional problems of living systems.

Thus, the idea of biomimesis (or homeotechnology, or reverse engineering) conveys the awareness that, while, thus far, technology has been primarily used to modify nature, the rich sources of inspiration produced by almost 4 billion years of biological evolution have only begun to permeate technology and engineering. Biology supplies examples of immense sophistication, starting with the cell with its thousands of chemical reactions that enable it to interact, carry out a broad variety of functions and reproduce, and extending to the complexity of organs and organisms. There is also a long list of natural "inventions", like proteins, enzymes, DNA, membranes, fluids, sensory mechanisms, that can become a model for human design.

In the course of history we have used natural systems in various manners, as biological materials (leather, wood, bone etc.), as biological energy (pack animals), as biological sensors (watchdogs, birds etc.), and of course as micro-organisms in the context of fermentation and preservation. The prospects for biomimesis that are currently opening up are directed towards the molecular level, towards the building blocks, the proteins and biomaterials of living systems. As Ball (2001) argues, biomimetics has the potential to enrich many areas of technology, but requires an intimate understanding of natural mechanisms at the molecular scale. The idea is that in the near future it will become possible to imitate characteristics of living materials such as self-repair, self-assembly and recyclability. Indeed, the ultimate challenge in drawing inspiration from biological organisms is the creation of biomachines that can reproduce themselves.

10.5. Pervasive Applications: Philosophical Reflections

The basic profile of pervasive science is as yet highly ambiguous. On the one hand, novel developments seem to offer ample opportunities for the development of sustainable and nature-friendly technologies, for example through "ecogenomics" (the use of molecular and genomics technologies for improving our understanding of the functioning of ecosystems). On the other hand, these same developments may allow

us to strengthen our technological sway over nature (both inside and outside human bodies) by increasingly allowing us to interact and intervene with natural systems in intimate and tailored ways. A similar ambiguity emerges when we consider the bioethical and biopolitical implications of pervasiveness. On the bioethical level, it initially seems to favour empowerment by opening up new possibilities for self-management, creating new opportunities for developing what Michel Foucault has called "practices of the Self". We may begin to influence our molecular, physiological and cognitive systems more effectively than ever before. At the same time, it is clear that these developments offer new possibilities for biopolitics, that is: for top-down initiatives directed at the management of populations. For example, new technologies may permeate the bodies of psychiatric patients, top athletes or Alzheimer patients in order to restore or improve their functioning, through biomaterials or genetically modified viruses designed to produce neurotransmitters or other "natural" substances whenever our bodies are insufficiently able to do so. Such technologies may enhance the opportunities for individuals to manage their own condition, but may also open up avenues for manipulation by various institutions.

By remodelling their genomes ("synthetic biology"), viruses can be used for producing biomaterials. By adding gene segments to plant viruses, self-replicating, biomimetic enzymes can be generated, for instance for producing cellular energy (adenosine triphosphate, ATP), hormones (testosterone), enzymes (insulin) or muscle tissue inside human bodies. Viruses can be used as synthetic platforms for producing self-replicating compounds or for self-assembling enzymes and catalytic products that stimulate various cellular processes (Comellas-Aragones et al., 2007). Enzymes encapsulated in a virus can be used for biodetection inside human bodies or for setting up self-assembling systems for producing composite materials such as bone tissue (Kinsella & Ivanisevic, 2007). Thus, "nature's own approach" (self-assembly) is used to produce a broad variety of biomolecules (Carette et al., 2007). In laboratories, synthetic biology has already begun to pervade our bodies. In addition to therapeutic applications, other options come into view as well, notably in the context of special professions such as soldiers of the future, who may well be equipped with biosensors (miniaturised biomimetic sensing devices) or self-replicating systems for wound healing or intracellular production of biomolecules that increase strength, endurance and resistance to stress or disease. A report published by the National Research Council (2001) highlights how "pervasive" this research is becoming. Yet, beyond these "avant-garde" applications, more every-day, ubiquitous,

or life-world applications, involves therapeutic applications and prevention, are coming into view as well.

Since the original demonstration in 1999 that measured electrical activity generated by neurons can be employed to control devices such as computers or protheses, research on Brain-computer-interaction (BCI) has evolved at a stunning pace (Lebedev, 2006; Birbaumer, 2006). Applications focus on restoration of limb mobility in severely handicapped (paralysed) individuals through invasive and semi-invasive micro-recording devices. The focus is on revalidation (recovery of normal functioning), notably in the context of reduced mobility by providing subjects with feedback signals derived from their own brain activity, deciphering intentions through measuring the electrical activity of massive neuronal populations (Scott, 2006). In the future, researchers envision that they will be fully implanting recording systems that wirelessly transmit multiple streams of electric signals derived from neurons.

Although the present context of application is mainly therapeutic, there are no obstacles, technologically speaking, to using these same techniques for enhancement in healthy individuals, thus pervading the realm of normal functioning, notably in situations where natural functioning seems unable to deal with the increasing complexities of emerging devices. A classical example is the fighter jet pilot. These pilots find themselves increasingly challenged by the swiftness and complexity of aircraft mobility. Some of the "deficiencies" of human behaviour (such as misguided impulsive responses) may not be amendable by training or by external equipment. Biomimetic electrodes may then be implanted as life-saving devices to overrule and counteract the pilot's "inadequate intentions". Again, our focus will be on more everyday scenarios involving techniques that may be employed for signalling and counteracting stress, depression and ADHD or other behavioural issues.

A bottleneck is the development of fully implantable biocompatible devices for recording electrophysiological activity by brain-derived signals. It is precisely here that some of the trends outlined in this paper may converge. The primary objective would then be to develop electrodes that become increasingly indistinguishable from their neural environments, produced from viral genomes to which particular gene segments are added for the production of biomaterials through self-assembly. Thus, both trajectories eventually converge in a boundary zone where biomaterials facilitate 'performance enhancement', giving rise to 'Science-fiction like scenarios'.

Big international companies such as IBM are developing futuristic playgrounds where pervasive technologies permeate everyday

environments, connecting a plethora of novel devices in an apparently seamless computing environment. Pervasive computing is the technology that tries to make this possible. Islands of technologies are gradually converging into a comprehensive technological environment. In the near future, computing will no longer be an activity that is conducted behind desktops. Rather, an omnipresent network of devices is expected to facilitate all functions of life. The basic question once again is whether this will enhance empowerment (self-management) or rather discipline and control (embedding human individuals as "elements" in digital networks). Human-computer interaction (HCI) is a research field involving issues of design, evaluation, adoption, and actual use of new information technologies. Emerging digital environments may come to include devices for diagnostics and prevention, thus enabling individuals (belonging to patient groups, risks groups, special professions, etc.) to monitor their health and condition, thereby providing tools for Self-management, but it may also allow Big Brother to monitor our behaviour more effectively than ever before. At a certain point, with the help of biomaterials (bioelectrodes, bioimplants, etc.) these technologies may begin to enter the bodies, blurring the boundaries between technology and Self.

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Part 4. The Dimension of Regulation Type

Chapter 11. 'Trust me, I'm a Regulator': the (In)adequacy of EU Legislative Instruments for Three Nanotechnologies Categories

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Abstract
Growing demand for new and/ or improved products has encouraged governments and industry to experiment with innovative technologies, such as nanotechnologies, across the manufacturing chain. With nanotechnologies destined to impact on every aspect of society, there is increasing concern that the very novelty which defines this platform technology will itself bring new and unforeseen risks. In light of this discourse, this paper examines the European Union's regulatory frameworks for cosmetics, medical applications and food contact materials in order to determine their suitability for regulating nanotechnology-based products and their associated (potential) risks. While the strengths of these current regimes are noted, a number of important gaps within each framework are identified. Initial steps for addressing these gaps that take into consideration both the need to protect against potential risks and the broader interests associated with the development of the technologies are outlined.

11.1. Introduction[1]

The growing demand for new and/or improved products, including those that address urgent societal and global problems, such as climate change, increasing dependency on alternative energy sources, access to clean water, and meeting the health challenges of an aging population, have encouraged governments and industry to experiment and incorporate innovative technologies across the manufacturing value chain. Emerging technologies that promise to assist society address these and many other challenges include information and communication technologies (ICT), biotechnology, and cognitive sciences. Each of these areas of endeavour will unquestionably provide novel products and solutions to current and future challenges. However, it has been argued that one such emergent technology, nanotechnology or nanotechnologies, will give rise to another technological 'revolution' (see generally Sparrow, 2008). Putting aside

[1] The authors would like to gratefully acknowledge the support of the Research Fund K.U. Leuven.

the hype and hyperbole that often surrounds discussions of nanotechnologies, it can be reasonably foreseen that the ubiquitous nature of nanotechnologies and its ability to be utilised across all industry sectors – from aerospace and agriculture, to electronics, military and medical applications – will ensure the rapid commercialisation of products and applications produced by nano-manufacturing processes or incorporating nanomaterials. Moreover, with leading industry commentators speculating that products incorporating nanotechnologies across the value chain will have an economic value in the vicinity of US$ 1.0-2.4 trillion by 2015 (Roco and Bainbridge, 2001; Lux Research, 2005), the impact of this platform technology appears destined to increase alongside its commercialisation.

With nanotechnologies predicted to impact on every aspect of society, there is increasing concern that the very novelty which defines the technology, a consequence of the unique properties of chemical substances that appear at the nanoscale and the exploitation thereof will itself bring unforseen human and environmental health and safety risks (see generally Oberdörster, 2004; Maynard, et al. 2006; and Kandlikar, et al. 2007). While validated scientific studies remain limited, though such data gaps are being rapidly addressed by the research community, there is evidence to suggest that, for example, some engineered nanoparticles may be more toxic than their larger scale counterparts (Oberdörster, et al., 2005) due to the nanoparticle's higher surface area to volume ratio and the subsequent increase in the proportion of atoms on the particle's surface (Nel, et al., 2005). However, size is just one of a number of potential physio-chemical characteristics that may influence the toxicity of nanoscale, with Oberdörster, et al. (2005) having suggested a number of other parameters that may be important in determining toxicity including, the nanoparticle's shape, agglomeration state, and surface chemistry.

As government, industry and scientists race to determine and evaluate the potential scientific risks posed by some aspects of nanotechnologies, particularly the risks posed by free engineered nano-particles (i.e. those not embedded into a fixed matrix), there have been increasing calls for governments and other stakeholders to evaluate the adequacy of current regulatory regimes for the various current and future applications of the technology. In response to these calls, governments in several jurisdictions have initiated either in-house or commissioned independent regulatory reviews, each of which has been designed to determine the appropriateness of these regimes for managing the potential risks of the technology (Chaudhry et al., 2006; Food and Drug Administration, 2007; Environmental Protection

Agency, 2007; Ludlow, Bowman and Hodge, 2007; and European Commission, 2008a, 2008b). At the same time, a number of commentators have expressed their concern over perceived limitations and gaps within these frameworks (see, for example, Kimbrell, 2006; Davies, 2006; Taylor, 2006, 2008; Friends of the Earth Australia (FoEA) 2006, 2008). In light of the increasing international discourse within this area, there is increasing pressure from all sectors of society to determine how nanotechnologies are, and will be, regulated as they evolve. This situation, as observed by Levi-Faur and Comaneshter (2007: 150), is somewhat unique, with the authors noting that, "unlike other cases where the discussion of the associated risks has followed the development of new technologies, the discussion on the proper regulatory framework for the governance of nanotechnology risks is accompanying the development of the technology and the associated products themselves". As such, a rare opportunity exists for stakeholders actively to participate in the development of a regulatory framework or frameworks for nanotechnologies.

In light of this discourse and given the uncertainty as to the adequacy of current regulatory frameworks with respect to certain domains of nanotechnologies, a four year research project was initiated in December 2007 at K.U. Leuven Law School. The intent of this research project is to evaluate the suitability of existing European Union (EU) regulatory frameworks for regulating current and future nanotechnology-based products within three distinct areas – cosmetics, food and food contact materials (FCMs), and medical applications. Where gaps and weaknesses are observed within each of these regulatory regimes, the project is developing a revised, workable, regulatory framework, which will not only adequately regulate nanotechnologies, but may also serve for other emerging technologies.

This chapter reports on the findings of Years One and Two of the project (finalised early 2009), where the focus was the evaluation of existing regulatory frameworks for cosmetics, foods, and medical applications. These case studies are presented in Section 2 of the chapter. In Section 3, a number of initial steps for addressing these gaps that take into consideration both the need to protect against potential risks, and the broader interests associated with the development of the technologies, are outlined. In Section 4, the chapter briefly examines the potential role for regulatory innovation in addressing some of the current shortcomings of the current regimes, and the appropriate role of the precautionary principle in regulatory strategies relating to the three case studies. The paper concludes in Section 5 by focussing on what we consider to be the next steps to be

initiated as part of the emerging regulatory landscape so that the technology can be effectively regulated as we move forward.

11.2. Regulatory Challenges Posed by Nanotechnologies: A Case Study Approach

11.2.1 Cosmetics

Increasing consumer demand for cosmetic products that exhibit enhanced aesthetic and functional qualities has resulted in an escalating interest by the industry in the use of nanotechnology within cosmetic formulations. Current products which claim to incorporate engineered nanomaterials include, for instance, anti-ageing creams, make up, hair care products, cleansers and moisturisers. It is thought that these products contain an assortment of engineered nanomaterials ranging from metal oxides, fullerenes, quantum dots, liposomes, and nanospheres in order to create products that are more visually pleasing, have superior colouring effects or are easier to spread. Yet despite the reported wide-spread use of nanomaterials within the cosmetic industry,[2] the exact nature and extent to which engineered nanomaterials are being used by the cosmetics industry remains somewhat ambiguous (Scientific Committee on Consumer Products (SCCP), 2007).

While the use of engineered nanomaterials within cosmetics offers a range of benefits, there has been increasing debate within the scientific and non-scientific literature over the potential health and safety risks associated with their use in topically-applied formulations (see Therapeutics Good Administration, 2006, 2009; Nohynek et al., 2007; Nohynek, Dufour and Roberts, 2008; Environmental Protection Agency (EPA), 2009; also Fleming, 2006; Kimbrell, 2006, 2007; FoEA, 2006; International Risk Governance Council, 2008, 2009). Such concerns are not unique to the cosmetics sector. However due to the direct application of cosmetic and personal care products onto the human body, and the lack of scientific certainty surrounding the potential toxicity, fate and effect of many nanomaterials (Maynard 2007), it would appear that the use of nanomaterials in cosmetics products have received additional attention from some organisations. This is despite the fact that these products are subject to regulatory controls within every jurisdiction in which they are sold, including the EU.

To date, the specific concerns raised by commentators, especially in relation to the use of insoluble nanoscale metal oxides have focused on the lack of scientifically sound data on the ability of insoluble

[2] See, for example, the Project on Emerging Nanotechnologies' Consumer Project Inventory (2009).

nanoparticles to penetrate the stratum corneum, pass into the viable epidermis and enter the vascular system; and the potential consequence, in terms of hazards, should absorption and translocation occur (Hoet, Bruske-Hohlfeld and Salata, 2004; and Oberdörster, Oberdörster and Oberdörster, 2005). Questions have also been raised by a number of scientists, policy makers and members of the NGO community in relation to the adequacy of conventional safety assessment methods for cosmetic ingredients, and the appropriateness of these risk assessment paradigms for all, but in particular insoluble, nanomaterials used in cosmetics (see, for example, SCCP, 2005; Santamaria and Sayers, 2010; Chaudhry, Bouwmeester and Hertel, 2010).

In light of these questions and concerns, an examination of the EU's regulatory framework for cosmetic products, as governed primarily by Council Directive 76/768 EEC (the Cosmetics Directive) and its subsequent amendments, was undertaken in order to determine the suitability of the regime for regulating cosmetics containing nanomaterials. Given the concerns that have been raised in relation to different classes of engineered nanoparticles being used in topically applied products, the review looked at the operation of the framework for two different types of nanotechnology-based cosmetic products: firstly, reformulated make up products containing insoluble metal oxide nanoparticles, such as foundations, concealers and eye-shadows, which are specifically designed to stay on the outer layer of the skin; and secondly, anti-wrinkle creams containing biodegradable polymeric nanoparticles, such as nanocapsules[3] and nanospheres, which are used to deliver active ingredients to their target site. Such particles are designed specifically to penetrate the stratum corneum while simultaneously masking or modifying the physio-chemical properties of the active substance(s) that they contain.

While the Directive has since been superseded by the November 2009 adoption of the Cosmetic Regulation by the European Parliament and Council (as will be discussed in more detail below), many of the findings of the review remain valid not only to the European Union at this time – given that the Regulation will not enter into force until 2011 – but also other jurisdictions with similar regulatory arrangements to that of the EU under the Cosmetic Directive. By replacing some 3500 pages of legal text and 27 transposing pieces of national legislation with one Regulation, the Commission hopes to ease administrative problems, remove national differences that do not contribute to

[3] Bouchemal et al. (2004: 93) notes that 'the size of nanocapsulates is usually bound to be between 100 and 500 nm'.

product safety and minimise the uncertainties and inconsistencies that have plagued the operation of the Directive.

As noted by the EU itself, the current regulatory regime underpinned by the Directive consists of a 'patchwork of more than 45 amendments with no set of definitions and no coherent terminology.'[4] In accordance with its main objective – 'the safeguarding of public health' – the Cosmetics Directive and its amendments set out the legal requirements and principles pertaining to cosmetic products within EU Member States, including those relating to 'composition, labelling and packaging of cosmetic products' (Preamble, at 3). As established by the Cosmetics Directive, any cosmetic product put onto the market within the European Union must not pose a risk to human health when used 'under normal or reasonably foreseeable conditions' (Article 2). Failure to comply with this legislative requirement will result in the manufacturer or importer being held liable for any damage caused by the unsafe cosmetic product or products (see Article 4a(1) and Article 7a(d)). For these reasons alone, it is in the industry's best interests to only develop and place onto the European market products that are safe and conform to the requirements of the Directive.

Despite the focus on safeguarding public health, the Cosmetic Directive did not establish any pre-market registration, approval or review requirements for determining the safety of a cosmetic product prior to its entry on the European market. This situation is not unique to the EU, with jurisdictions such as the US and Australia having similar limited, if any, pre-market regulatory requirements including safety testing, for cosmetic products (see, for example, Taylor, 2006; Ludlow, Bowman and Hodge, 2007). Moreover, this situation will not be altered under the adopted text of the Cosmetic Regulation. As set out in Article 7 of the Cosmetic Directive, pre-market requirements are instead limited to the data notification requirements and rigorous safety requirements and evaluations standards for the manufacturer/importer/marketer. Control over certain ingredients and their use in cosmetics is dealt with under Article 4 of the Directive, which provides for the establishment of 'positive', 'negative' or 'restricted' lists in the Directive's Annexes. Substances are listed and therefore regulated on the basis of their name; the lists do not, for example, differentiate between substances of the same chemical formula that differ in size. Regulation by reference to chemical identity and not size is important in relation to the use of nanoparticles in cosmetics formulations.

[4] It is of no surprise therefore that due to the regulatory burden associated with the Cosmetic Directive, the EC has proposed that the Directive be recast as a Regulation. As the exact nature and content of the proposed recast is unlikely to be known for some time, the review focused on the current regulatory regime.

Prime facie it is possible to assume based on the existence, structure and function of the regulatory regime that all cosmetics products incorporating engineered nanoparticles available in the European market are safe and do not pose a risk to the health of the consumer when used for the purpose for which they were manufactured. But is it really that simple?

As outlined above, many within the cosmetic industry have already begun to substitute microsized particles, including titanium dioxide (TiO_2) and zinc oxide (ZnO), with their nanoscale equivalents. The purpose of the substitution is to improve the aesthetic and or functional nature of the cosmetic formulation. Within the EU the process by which the safety is assessed of active ingredients within a cosmetic product is set down in the EC's SCCP (2006) *Notes on Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation* (Guidance Notes). This framework provides the evaluation regime for cosmetic products. While the Guidance Notes apply to all active ingredients contained within a cosmetic product, including nanoscale metal oxide particles such as TiO_2 and ZnO, as noted by Chaudhry, Bouwmeester and Hertel (2010: xx) in relation to the risk assessment paradigm generally, "it has been pointed out that the current testing methodologies would need certain adaptations in view of the special features of [engineered nanomaterials], e.g. the insoluble particulate nature, possible agglomeration, binding of other moieties on particle surface etc".

The suitability of existing risk assessment for engineered nanomaterials in cosmetics as well as other products has been considered by several of the European Commission's Scientific Committee's, including the SCCP (2007) and the Scientific Committee on Emerging and Newly Identified Health Risks (2006, 2009). In their report, the SCCP (2007: 38) concluded that 'there are large data gaps in risk assessment methodologies with respect to nanoparticles in cosmetic products'. In reaching their opinion on the safety of nanomaterials in cosmetic products, the Committee (2007: 35) sought to differentiate between two different types of nanoparticles:

1. soluble and/or biodegradable nanoparticles, such as polymeric nanoparticles, which are discussed in more detail below), and
2. insoluble and/or biopersistent particles, such as nanoscale titanium dioxide.

The Committee (2007: 35) concluded that, "[f]or the first group, conventional risk assessment methodologies based on mass metrics may be adequate, whereas for the latter other metrics such as the number of particles, and their surface area as well as their size distribution are also required". In light of the current uncertainties

surrounding the suitability of existing risk assessment for the purpose of evaluating toxicity and therefore human safety of the nanoparticles as provided for in the SCCP's Notes on Guidance, questions over the adequacy and/or appropriateness for calculating potential risks – especially in relation to toxicity – for some nanoparticles remain. This would appear to be particularly so in relation to the use of, for example, nanoscale ZnO and TiO_2. It is not surprising therefore that the SCCP (2007: 6) concluded that, "it [is] necessary to review the safety of nanosized TiO2 in the light of recent information and to consider the influence of physiologically abnormal skin and the possible impact of mechanical action on skin penetration".

Given that cosmetic products containing this type of engineered nanoparticle have already made their way into the European market it would appear that the Cosmetics Directive and the SCCP's Notes of Guidance may not be adequate in their current form for regulating this category of nanoparticles when used as ingredients in cosmetic products. Accordingly, while the Cosmetics Directive requires that any cosmetic product put onto the market within the European Union must not pose a risk to human health when used 'under normal or reasonably foreseeable conditions', it appears unlikely that manufacturers and or importers of nano-cosmetics cannot – when based on the assumption that appropriate risk assessment protocols have not yet been devised or carried out – guarantee the immediate and longer-term human safety of their cosmetic products that contain insoluble and/or biopersistent nanoparticles at this time. This uncertainty is clearly problematic from a public health perspective.

The current situation of insoluble mineral-based engineered nanoparticles in cosmetic products may be contrasted to that of the second type of nanomaterial used in cosmetics examined in the review: polymeric nanoparticles. As explained by the SCCP (2007: 59), nanocapsules "can be: chemical/drug targeted delivery systems that release the ingredient when arrived at the site in the body where it is required, chemical/drug timed release delivery where the nano-encapsulated material slowly allows the ingredient to be released into the body, increased shelf life and stability of fragile chemicals". This enables biologically active ingredients to be transported to areas of the body that have been traditionally inaccessible and at quantities that have been conventionally unachievable (Soppimath et al., 2001; Honeywell-Nguyen and Bouwstra, 2005; SCCP, 2007; Guterres, Alves and Pohlmann, 2007). Since 1995, leading cosmetic companies such as L'Oreal have been using polymeric nanoparticles as carrier systems in existing cosmetic products, in conjunction with developing innovative new products (Small Times, 2002).

Nanocapsules appear to offer the cosmetic industry a superior carrier system when compared to earlier generations of delivery systems for highly unstable active compounds sensitive to oxidation such as the vitamin A derivative retinol (Jenning et al., 2000: 211). Benefits offered by this newest generation of nanotechnology-based formulation include, for example, increased penetration rate of the active ingredient into the stratum corneum, increased stability of active ingredients (Soppimath et al., 2001), and greater control of the release of substance (Guterres, Alves and Pohlmann, 2007). Publically available scientific information at this time suggests that nanocapsules and other soluble nano-sized structures are unlikely to present any new risks to human health when used in cosmetic products, with the SCCP (2007: 5) having stated that "it is primarily for the insoluble particles that health concerns related to possible uptake arise". This is primarily due to the soluble/biodegradable nature of these particles, the SCCP (2007: 17) noting that, "a series of independent studies have concluded that the vesicles themselves used by the cosmetic industry do not penetrate beyond the most superficial layers of the stratum corneum, but break down". As such, while the Cosmetics Directive and the testing and safety evaluation procedures set out in the Guidance Notes do not differentiate these structures from their chemical equivalents on the basis of scale, it would appear that this in itself is less problematic from a human health and safety point of view when compared to insoluble/ bio-persistent nanoparticles. However, that being said, questions over the appropriateness of current testing methodologies and the potential risks associated with the fate of the capsules still remain at this time (Honeywell-Nguyen and Bouwstra, 2005; SCCP, 2007).

In light of these concerns, the review concluded that under the Directive, and therefore analogous regulatory frameworks in other jurisdictions, the *potential* exists for what may be unsafe nano-based cosmetic products to be placed on the market. However in reaching this conclusion a number of important caveats must be articulated. First, for this conclusion to hold true, it must be first shown that the nanoparticles can and do penetrate the stratum corneum, pass into the viable epidermis and enter the vascular system, and that the particles are hazardous to individuals and elicit an effect when absorption and translocation occur. Moreover, in reaching this theoretical conclusion based on an academic review of the regulatory framework and incomplete scientific knowledge, it is important to also differentiate between the different categories of engineered nanoparticles being incorporated into cosmetic products. With respect to cosmetic products utilising soluble or biodegradable nanoparticles such as

polymeric nanoparticles within, for example, anti-wrinkle creams, it would appear that – based on current scientific evidence – the Directive is *most likely* to be adequate for safeguarding consumer's health and safety. In contrast the review concluded that based on the current scientific evidence, and the major data gaps relating to exposure, toxicity and risks, the Cosmetics Directive *may not* be sufficient to ensure the safety of cosmetic products incorporating insoluble or bio-persistent nanoparticles such as nanoscale metal oxide particles, *should* update and translocation of the particles occur, and should these particles be proven to be hazardous.

As noted above, in November 2009 the European Parliament and Council adopted the final text of the Cosmetic Regulation. From our perspective, one of the key components of the final text is the fact that the regulator sought to differentiate cosmetics containing nanomaterials from those that do not. Obviously such action required the introduction and general acceptance of what constitutes a 'nanomaterial' for the purposes of the Regulation. Pursuant to Article 2(1)(k) of the Regulation, a 'nanomaterial' will be defined as "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm". Upon the Regulation's entry into force, the responsible person for placing a new cosmetic product containing nanomaterials (as defined above) onto the EU market will be required to – in addition to all other requirements – notify the Commission of the presence of the product and supply certain safety information to the Commission six months prior to its entry onto the market. Similarly, manufacturers of nanoscale cosmetic products which are already in the market will be required to notify and submit safety data to the Commission (Article 16(3)). Should the Commission have concerns about the safety of the nanomaterial in use, they will be required to seek an opinion from the SCCP (Article 16(4)); and any such opinion must be made publically available (Article 16(4)). This, as eloquently stated by Gergely and Coroyannakis (2009: 30), "will ensure a case-by-case review, whereby safety will remain the number one priority".

The Regulation also requires the Commission to create a publically available catalogue of "all nanomaterials used in cosmetic products placed on the market... and the reasonably foreseeable "exposure conditions" (Article 16(10)(a)); and to submit an annual status report to the Parliament and Council on the "developments in the use of nanomaterials" in the EU market (Article 16(10)(b)). These provisions are clearly aimed at addressing concerns over the lack of transparency in relation to nanomaterials in consumer products. In addition to these

requirements, any products containing nanomaterials, as defined by the Regulation, must indicate the presence of the nanomaterials in the list of ingredients. This will be done by placing the word 'nano' in brackets after the nanoscale ingredient. No threshold limits have been established by the Parliament and Council in relation to this labelling requirement. As such it would appear that even if the nanomaterial constitutes, for example, less than 0.5 per cent of the product, the label on the cosmetic product will have to indicate the presence of the nanomaterial by the inclusion of 'nano' (in brackets) following the chemical identity's name. This would also appear to hold true even when the nanomaterial is present only in a trace amount (Bowman, van Calster and Friedrichs, 2010).

11.2.2 Foods

The convergence of nanotechnologies with the food and food processing sector is expected to revolutionise the global food supply from farm to fork, and be a "significant ingredient in the food industry" (Wolfe, 2005). With "virtually every major food company [already] involved in nanotech R&D" (Wolfe, 2005), it is not surprising that the ETC Group (2004: 3) have reported that "food products containing nano-scale additives ... are already on the grocery store shelf". Offering an economically competitive benefit and unimaginable potential across the entire breadth of the agri-food sector, it is unsurprising that significant economic growth in the sector is anticipated.

Unlike the intense debate surrounding the use of biotechnology within the agri-food system, foods incorporating nanotechnologies have largely, until recently that is, entered the commercial market under the media and public radars. An exception to this is the review undertaken by the Friends of the Earth Australia Nanotechnology Project (Miller and Senjen, 2008), as well as the publication of several more recent reports by organisations such as the UK House of Lords Science and Technical Committee (2010). Looking specifically at the FoEA review, the comprehensive report identified over one hundred products containing engineered nanoparticles, including food processing technologies, delivery systems, food contact materials, and agrochemicals. In highlighting the range of commercially available agri-food products containing nanotechnologies, the report noted a range of human and environmental health and safety uncertainties associated with the use of nanotechnologies within the sector, including those relating to toxicity and exposure. Despite the existence of legislative frameworks in jurisdictions such as the EU that regulate different aspects of these products in order to safeguard public health, the authors of the report argued for a "moratorium on the further

commercial release of food products, food packaging, food contact material an agrochemicals that contain manufactured nanomaterials until nanotechnology-specific safety laws are established" (Miller and Senjen, 2008: 3). Concerns raised by organisations such as FoE, in relation to the use of nanotechnologies in food would appear to focus on the ability of nanoparticles to be absorbed from the digestive system into the vascular system, and the potential consequences, in terms of hazards, should absorption and translocation occur. Unsurprisingly, questions have also been raised in relation to the ability of the existing regulatory frameworks adequately to manage any potential risks associated with the use of nanotechnologies across the agri-food sector in both the short and the medium term.

While a number of regulatory reviews have now been initiated within the EU, many of which have included the agri-food sector within their scope (see, for example, Food Safety Authority of Ireland, 2008; Food Standards Agency, 2008), a number of questions remain. This is in part due to the dynamic nature of the European regulatory system, with a number of relevant regulatory instruments having been recently revised, and several other instruments, including Regulation (EC) No. 258/97 (the Novel Foods Regulation) going to be recast. In light of the lingering questions, an examination of the EU's regulatory framework for foods, novel foods, food additives, and food contact materials was undertaken as part of the review (see Gergely et al., 2010a, 2010b). Due to space limitations, this section of the chapter will only report on the findings of two areas of examination: regulatory aspects relating to foods generally and food additives.[5]

One of the most relevant legislative instruments to the regulation of nano-foods is Food Law Regulation 178/2002, which sets down the general principles and requirements of food law within the Community, as well as providing the statutory basis for the establishment of the European Food Safety Authority. Pursuant to Article 14(1) of Regulation 178/2002, food cannot be placed on the European market 'if it is unsafe'; it is also ineligible for marketing if the food contains substances harmful to health. Failure to comply with this legislative responsibility will result in the seller being held liable for any damage done by the unsafe food article or articles. This ultimate responsibility provision operates regardless of whether or not the food was manufactured using nanotechnology-based food processing methods or incorporates nanoparticles. *Prime facie* it is possible to conclude that the general safety articles embodied within Regulation 178/2002 will, by implication, encompass foods containing nanomaterials and/or

[5] For an in-depth review of the findings, see Gergely et al. (2010a, 2010b).

manufactured using nanotechnology. However, while nano-foods will clearly fall within the regulatory scope of Regulation 178/2002, the question remains as to the adequacy of conventional protocols for establishing the safety of any such food prior to its entry onto the market.

At the time of the review (July 2008), food additives were regulated by Framework Directive 89/107 (the 'Food Additives Framework Directive') and a number of pieces of subordinate legislation. Pursuant to the Framework Directive, nanoscale food additives were 'assessed either as novel additives or, where a macro-equivalent is already approved, through potential amendments of the appropriate specifications, including purity criteria, under the Directive 96/77/EC' (Gergely et al., 2010a).

Gergely et al. (2010a) have, however, noted that from 2010 onwards the Framework Directive will be replaced by a common authorisation system for food additives, food enzymes and food flavourings (see Regulation (EC) No. 1332/2008, Regulation (EC) No. 1333/2008 and Regulation (EC) 1334/2008). The new system will bring together the existing food additive regulations and introduce comitology for the approval of the three substances (Gergely et al., 2010a, 2010b). Under the common authorisation system, all applications for the approval of each category of substance will be directed to the European Food Safety Authority (EFSA), which will be required to carry out the safety evaluations and risk assessment (Chaudhry et al., 2008). Pursuant to the new system, a positive-list ('Community list') will be established for each substance category. As noted by the EC (2007: 3), 'the inclusion of a substance on one of these lists means that its use is authorised in general for all operators in the Community'.

Importantly, under this new common authorisation system, EFSA will be invested with the necessary power to re-evaluate a safety assessment. This may have important implications for nano-scale food additives (Chaudhry et al., 2008; Gergely et al., 2010a, 2010b). Food additives – once approved – will be kept under continuous observation and re-evaluation wherever necessary. Moreover, producers or users of food additives that are 'significantly different from those include in the risk assessment of the Authority or different from those covered by the specifications laid down' will be obliged to inform the Commission of any new information that may affect the safety assessment of a food additive (Chaudhry et al., 2008; Gergely et al., 2010a, 2010b). As suggested by Gergely et al. (2010a: 157), 'significant difference' could mean *inter alia* a change in the manufacturing process or in specifications, changing conditions of use, any new scientific

information, or 'a change in particle size'.[6] This definition arguably implies that the use of nanotechnologies will constitute a 'significant difference' for the purpose of re-evaluation by the EFSA. Gergely et al. (2010a, 2010b) have therefore argued that this is an important inclusion in the new system. Pursuant to the new Regulations, EFSA will also be invested with the power to re-evaluate a food additive on the basis of 'new scientific information' (Regulation 1333/2008). While it was unclear at the time of review whether or not 'new scientific information' would be interpreted to include development in nanotechnology, it is argued that the express inclusion of 'change in particle size' might be relevant for triggering re-evaluation by the EFSA (EC, 2008; Chaudhry et al., 2008; Gergely et al., 2010a, 2010b).

Following its review of legislative measures for nanomaterials in cosmetics, the European Parliament also voted in March 2009 in favour of a report dealing with an update of the EU rules on novel foods, which also proposes special treatment for nanoparticles and nanomaterials (EP vote on COM(2007) 872). According to the proposal, nano-specific test methods should be developed as a matter of urgency and nanomaterials present in food packaging should be entered on a list of approved nanomaterials, accompanied by a limit on migration into or onto the food products contained in such packaging (meaning in practice that until such methods have been developed, no such materials will be allowed on the market – in other words, a moratorium). The definition of a 'novel food' has been amended to include food containing or consisting of engineered nanomaterials, however MEPs did not support the inclusion of terminology referring to 'produced with the aid of nanotechnology'. All ingredients present in the form of nanomaterials will have to be clearly indicated in the list of ingredients. It is not clear at the moment whether Parliament will have enough support from the Council for it to push through its proposals.

11.2.3 Medical Products and Devices

Medical devices are regulated by Directive 93/42/EEC (the Medical Devices Directive);[7] Directive 90/385/EEC (the Active Implantable Medical Devices Directive);[8] and Directive 98/79/EC (the In Vitro Diagnostic Medical Devices Directive).[9] Directive 2007/47/EC[10]

[6] See Preamble 12 of the proposed Regulation 8/2008 in relation to food enzymes.

[7] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ [1993] L169/1.

[8] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ [1990] L189/17.

[9] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ [1998] L 331/1.

amended Council Directive 90/385/EEC, Council Directive 93/42/EEC and the Biocidal Products Directive (98/8/EC)[11] in September 2007, but does not make any amendments to the In vitro Diagnostic Directive. 'All three are also firmly based on a principle of risk analysis and risk management and utilise a supporting voluntary harmonised European Standard, EN ISO 14971' (Moore, 2009).[12] To date, the two main types of nanomedicinal products that are being commercialised are diagnostics and biomaterials. As such, the review focused on the operation of the relevant regulatory framework when faced with these two types of nanotechnology-based medicinal products: CellTracks and AcryMed's SilvaGard Antimicrobial Surface Treatment. CellTracks is an in vitro diagnostics technology developed to capture rare cells efficiently and reproducibly to enable accurate counting and molecular research, which has been incorporated into diagnostic equipment. AcryMed's SilvaGard Antimicrobial Surface Treatment is a silver nanoparticle technology created and applied in solution, which claims to provide an easy, cost-effective method of applying a surface treatment of ionic silver to a device.

As advances in nanomedicine and nanomedical devices are made, there are increasing concerns over the potential health and safety risks associated with their use, application, insertion and contact with the human body. The medical sector has traditionally been one of the most regulated, however nanomedicine raises unique challenges due to the lack of scientific data pertaining to toxicity and potential health effects, as well as concerns on the adequacy of existing regulation and standards in regulating nanomedicine.

CellTrack technology has been incorporated into the diagnostic equipment, 'The CellTracks Analyzer', which can be described as an automated differential cell counter that uses laser technology to enumerate and characterize cells based on morphology and fluorescent signatures. The CellTracks Analyzer is Immunicon's second-generation analyzer and is designed to be used in conjunction with the CellTracks AutoPrep System for sample preparation. In combination, these form a group of advanced diagnostic equipment using CellTrack reagent technology platform technologies for the selection and analysis of rare

[10] Council Directive 2007/47/EC – OJ [2007] L 247/21. Member States have until 21 December 2008 to transpose the new Directive into national law, following which there is a transition period for manufacturers to come into compliance by 21 March 2010.

[11] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ [1998] L 123/1.

[12] ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

cells in blood and potentially other bodily fluids. The Immunicon Corporation has been certified under the Quality management systems for medical device manufacturers (ISO 13485:2003) and CellTracks Analyser received US Food and Drug Administration (FDA) approval as well as the CE mark under the In Vitro Diagnostic Medical Devices Directive (IVDD). It has also recently made its first commercial shipments of the CellTracks(R) Analyzer II to Europe.[13]

The use of reagents and interrelated devices for diagnostic purposes in the EU is regulated by Directive 98/79/EC (IVDD).[14] Under this framework, the diagnostic device or reagent must meet the conformity and quality assessments required by the Directive depending on the class[15] before it can receive a CE Marking. After receiving a CE mark an *in vitro* diagnostic device is considered to have satisfied defined language, safety, quality, and performance requirements for EU Member States. All *in vitro* diagnostic devices must meet the applicable 'essential requirements' on safety, performance and labelling as outlined in Annex I of the IVDD. These safety requirements include criteria to address risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, risks of infection to the user or other persons and if the device is intended for use in combination with other devices or equipment, the whole combination, must be safe and must not impair the specified performances of the devices.

Prime facie, it would appear that such diagnostic devices are regulated by existing legislation. However, a closer examination of the regime suggests otherwise. IVDD applications are predominantly carried out on samples taken from the human body and analysed *in vitro* – risks can be said to be generally limited to usage, storage, transport and waste disposal. On the face of it, these risks are the same as the use of any other reagent or chemical. However, the uncertainty surrounding accidental release, toxicity and contamination by nanoparticles heightens the requirement for care. The applicability of

[13] Immunicon Ships First CellTracks(R) Analyzer IIs to Europe, available at: http://www.encyclopedia.com/doc/1G1-136442945.html. (accessed 26 February 2010)

[14] It covers devices used *in vitro* for the examination of a specimen derived from the human body, including reagents, instruments and specimen receptacles. The Directive aims to supplement the Community legal framework governing the conditions for the placing on the market of medical devices, by extending legislation to include *in vitro* diagnostic medical devices. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ [1998] L 331/1.

[15] *In vitro* diagnostic devices are classified under five classes with specific modalities to evaluate the conformity assessment, which, depending on the class, have to be followed before the device can receive a CE Marking. No *in vitro* diagnostic device can be placed on the market without a CE mark.

existing regulations relating to safety, pollution prevention and waste management has limitations as they are not specifically designed to deal with engineered nanoparticles.[16] Moreover, although the IVDD lays down the essential requirements for safety and risk analysis required for market conformance, it does not elaborate on them. Hence, these requirements can be complied with by means of quality systems and by adhering to published harmonised product standards. Most standards use mass concentrations to measure toxicity, and as noted above, such physico-chemical parameters may not be appropriate for nanoparticles, while conventional risk assessment paradigms may not be suitable for assessing the risks associated with nanoparticles. The review therefore concluded that the current standards and risk analysis methods being applied to nanodevices like CellTracks are inadequate for ensuring the safety of such devices. It was argued that existing safety and marketing standards must be reviewed and amended so as to specifically address the challenges posed by the use of engineered nanoparticles in such devices (see, for example, D'Silva and van Calster, 2009: 264).

As noted above, the second device considered within the context of the review was AcryMed's SilvaGard Antimicrobial Surface Treatment, a silver nanoparticle technology created and applied in solution, which SilvaGard claims provides an easy, cost-effective method of applying a surface treatment of ionic silver to a device. The devices can be treated to provide effective antimicrobial protection for days, weeks, or even months, depending upon the application requirements. Silver nanoparticles are generally used in the size range of 1.0-50 nm.

Despite the limited number of validated studies, specific concerns have been raised in relation to the potential health and safety risks. A study comparing nano-particle toxicity in mammalian germline stem cells, for example, found silver nanoparticles to be the most toxic of those tested, with the nanoparticles significantly reducing mitochondrial function and interfering with cell metabolism leading to cell leakage (Braydich-Stolle et al., 2005). The authors also showed that under certain conditions that when silver nanoparticles are used as antimicrobial agents in bone cement or other implantable devices, they may in fact be toxic to the bone-lining cells and other tissues. Recently

[16] The use of conventional practices for handling, safety and waste disposal of nanomaterials stems from a lack of information on the toxicological properties of nanomaterials, as well as nascent regulatory guidance regarding the proper environmental, health and safety practices that should be used with them. See ICON Report, "A Survey of current practices in the nanotechnology workplace" (2006), available at: http://cohesion.rice.edu/CentersAndInst/ICON/emplibrary/ICON_RNA_Report_Full2_Cond.pdf. (accessed 26 February 2010).

a silver-coated wound dressing Acticoat[17] (Smith & Nephew, Inc.) was introduced for use in burn patients. A study conducted on its toxicity has indicated that silver toxicity is possible and more studies are hence required (Trop et al., 2006). It is also unclear at this stage what effects incidental ingestion of silver nanoparticles might have on the digestive tract.

Antimicrobial surface treatments such as SilvaGard have a wide scope of application, and may therefore be incorporated into a range of medical devices. These devices will be regulated in accordance with Directive 93/42/EEC (the Medical Devices Directive or MDD). The MDD classifies the devices on the basis of potential risk.[18] On the basis of this classification various conformity assessments must be undertaken by manufacturers before the device is conferred a CE mark. For example, a catheter would be classified under Class III devices as high risk. Routes to compliance in that case are a full quality assurance system and examination of the design dossier, and the examination and testing of the product or production quality assurance. Manufacturers of medical devices must also carry out risk assessments, demonstrate the effectiveness of the device, and meet the essential safety requirements set out in Annex I of the Directive.

The existing medical device regulation appears to be stringent and unquestionably incorporates a wide range of safety and conformity requirements. But is it suitable for regulating devices incorporating nanoparticles? Arguable not. As illustrated by the CellTracks example, the concern and uncertainty lies in the usage of nanoparticles/ nanocoatings. SilvaGard technology may be used to treat virtually any medical device thus making its way across a wide spectrum of applications, instruments and devices. This type of universally applicable nanotechnology raises several concerns: firstly, that it will be used in medical devices that will come into direct human contact; and secondly, that the devices may be inserted into the human body for a prolonged period of time, as in the case of a SilvaGard coated catheter.

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[17] Antimicrobial barrier dressings for use over partial, full thickness and acute wounds using Patented Silver technology: SILCRYST Nanocrystalline, Product information available at http://www.acticoat.com/ (accessed 26 February 2010). It is a three-ply dressing, consisting of an inner rayon/polyester absorptive core between two layers of silver-coated, high-density polyethylene mesh. In a moist environment, the nanocrystals of silver are released and improve the microbial control in the wound.

[18] Medical devices are classified under 4 classes with specific modalities to evaluate the conformity. Class I – devices with low potential risk; Class IIa – with moderate potential risk; Class IIb – Devices with high potential risk; and Class III –- devices with critical potential risk. Compliance with the requirements of the Medical Devices Directive is declared by placing the CE Marking on the product and supplying the device with a declaration of conformity.

This application of nanotechnology has the potential to 'blur' the distinction between the mode of action on the human body as well as intended purpose of such products. It is also likely to further aggravate issues pertaining to the borderline between medical devices and medicinal products and further challenge the competencies of existing regulatory bodies. Another key issue, as discussed above, is whether the existing standards for testing, safety, usage and subsequent disposal address novel properties and likely concerns associated with nanomaterials. Medical devices are not designed to assess or evaluate unique aspects of nanoparticles and nanomaterials like size, shape or toxicity. In light of the current scientific concerns regarding nanoparticles, it would seem prudent for existing regulations to be reassessed and revaluated. This should be done on the basis of new and emerging scientific research and data on nanotechnology, given the uncertainties pertaining to novel properties, hazard evaluation, exposure evaluation and overall risk assessment (see, for example, SCHENIR, 2007; CHMP, 2006; N&ET, 2007; D'Silva and Van Calster, 2009).

It would appear that legislators in the EU will continue to regulate nanomedical products and devices under the existing regulatory regimes rather than create a completely new regulatory regime for nanomedicine. This would seem to be a logical step in the short term as the current regimes are relatively comprehensive. However, it is important to remember that these instruments were crafted prior to the emergence of nanomedicines, and as such, may need to be revised in the longer-term so as to take account of specific risks and challenges posed by nanomedicine. This revisionary or incremental approach seems to be the likely one EU legislators will take. The review also highlighted that the advancement of nanomedicines would appear to be blurring the boundary between medicines, devices and therapies, which is likely to be problematic in the medium to longer term from a regulatory perspective. Combination and borderline products may not readily fall into one specific regulatory system, and regulators will need to address the fact that the number of such products will only grow. These borderline products appear destined to also challenge the current criteria for classification and evaluation. Depending on the classification of medical device, medical product or therapy, different pre-market and post-market requirements are essentially required to be met. This has the potential to also impact upon pharmacovigilance requirements, post-market surveillance and the application of general harmonised standards.

While the various directives for regulating medical products and medical devices lay down a number of essential requirements that have

to be fulfilled before market authorisation, these are general and non-specific. The risk assessment, safety and quality requirements are to be fulfilled by conformity with established quality systems and published product standards that may not be suitable to address various concerns relating to nanomedicine. As progress in medicine and nanoscience accelerates in the manufacture and characterisation of nanoscale materials and nano-enabled products, it will become increasingly important for researchers, manufacturers, regulators and other stake holders to have agreed nanotechnology standards. Steps have been initiated for example in the case of the CEN/TC 352 to establish nano-standards, the effectiveness and adequacy of which are, however, yet to be ascertained. These standards will have to address the evaluation of the quality, safety, efficacy and risk-management of nanomedicinal products. Whether such standards, if introduced in the EU, will be in the form of broad guidelines or legally binding requirements, is however unclear at this time.

11.3. Initial Steps to Address the Regulatory Gaps

The reviews of the current regulatory framework for the three sectors highlighted a number of inadequacies in the current regulatory framework which need to be addressed.

Firstly, as is widely reported, there is a lack of scientific data as to the mid- and long-term impact of applications based on nanosciences. The 'simple' lack of scientific data and how this feeds into the regulatory cycle could be remedied relatively easily by taking the necessary risk management steps if and when more scientifically robust data on risks becomes available. It is of course noteworthy that in a precautionary approach (as discussed in section 4 below), one may advocate ban-type answers to such uncertainty as just described.

As will be apparent from the above analysis, the EU has, to date, opted for an incremental approach, whereby 'nano-hooks' have and are being attached to existing regulation, typically upon review of the regulations that had been scheduled for other reasons than that of addressing the nanotechnologies challenge. The advantage of having these hooks ready for use is evident, especially in the EU, where the preparation and adoption of new legislative instruments may be a slow, as well as hotly contested, process.

While the EU may have appeared fairly uncommitted to amending its regulatory framework in relation to nanotechnologies prior to 2009, actions by the European Parliament (EP) in April 2009 and the Parliament and Council in November 2009 would suggest – at least to us – that the MEPs and Member States have become increasingly

concerned about the impact of nanotechnology on their citizens. Accordingly, it would appear that the EU has positioned itself at the forefront of policy and regulatory developments in this area, and have done so with a bang. The EC could have introduced provisions within these legislative instruments that referred to, for example, generic terms such as 'particle size' as a trigger rather than 'nanotechnologies' *per se*, in order to avoid attention to its actions. In the absence of scientific evidence, such an approach would have been fairly harmless and largely symbolic. The path of least resistance will, however, now be left to other jurisdictions with the EU now appearing intent on adopting concrete measures to regulate nanotechnologies.

The inclusion or likely inclusion of the term 'nanomaterials' in key legislative instruments relating to cosmetics and food would suggest that the EP intend to place nanotechnologies firmly in the liability sphere along the lines of the recently adopted EC Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH), a primary objective of which was to reverse the burden of proof from the regulators to the regulated industry. This is not in itself a poor regulatory strategy, provided the authorities at the same time efficiently pursue the soundness of accompanying technical regulations, such as testing methods. With its response to these proposals, however, the European Parliament (at least in the case of cosmetics, with the express support of the Member States) has forced the Commission's hand and would like a much faster pace of development of risk assessment protocols. The Cosmetics Directive is a case in point. While one initial step to address identified gaps could be, for example, to modify the current safety requirements that underpin the Directive and the safety assessment framework set out in the SCCP's Guidance notes so as to require additional information and risk assessments to be undertaken on this family of nanoparticles, this in itself does not address the more fundamental issue – that the current risk assessment methodologies may be in themselves inadequate for assessing the risks posed by these particles. With the SCENIHR having concluded that 'current risk assessment methodologies require some modification in order to deal with the hazards associated with nanotechnology and in particular that existing toxicological and ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles', it would appear that until validated *in vivo* and *in vitro* risk assessment methodologies are developed for nanomaterials, including insoluble and bio-persistent nanoparticles, and incorporated into the regulatory framework, the potential for certain commercially available nano-cosmetic products to pose a risk to human safety will continue. The

development of these methodologies is surely an area in which public authorities on a global scale carry the brunt of the responsibility.

11.4. Regulatory Innovation and the Potential Role for the Precautionary Principle

As highlighted by sections 1-3, governments and commentators have to date largely focused on evaluating existing legislative frameworks and their adequacy for regulating the current generation of nanotechnologies, with fewer commentators having focused on the potential role or roles that other 'softer' regulatory mechanisms may play in regulating nanotechnologies now and in the future. This is not surprising given the embryonic nature of the technology and the uncertainties that exist in relation to the technology's developmental trajectories. However, as illustrated above, considerable doubt exists as to the extent to which state-based regulatory regimes are suitable for regulating different aspects of the technology and the subsequent ability of these regimes to protect human and environmental health and safety in the event that certain applications are proven to be hazardous. While traditional state-based, or 'command and control,' regulation, such as EU Directives and Regulations, provide certainty to the regulated and are often viewed by the public as being highly credible and more legitimate than other forms of regulation, it has for a while now been argued that this form of regulation also suffers from a number of shortcomings or weaknesses (Gunningham and Rees, 1997; Aalders and Wilthagen, 1997). Such formal regulation is seen, for example, as being too resource intensive, reactive, rigid, and lacking in creativity (Sinclair, 1997). Recognition that state-based regulation is only a part of the continuum and that other regulatory approaches, including co-regulation and self-regulation, exist is extremely beneficial when considering the different regulatory options for promoting the responsible development of nanotechnologies.

The scientific and regulatory challenges posed by nanotechnologies, and concern over the adequacy of the current state-based regulatory matrix for regulating nanotechnologies would appear to have prompted a number of government, industry and civil society stakeholders to examine the range of regulatory alternatives available to them. While governments have generally focused on the employment of 'voluntary reporting schemes' or voluntary 'stewardship programs' to assist in addressing the current knowledge deficit, the European Commission has been somewhat more innovative. It has, for example, designed and implemented its own *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* (EC, 2008c), albeit limited in

application. Codes of conduct have also been developed by a range of other actors including, for example, BASF, the Swiss Retailers Association, the Coalition of Non-Governmental Organisations, and the Royal Society in partnership with Insight Investment, the Nanotechnology Industries Association and the Nanotechnology Knowledge Transfer Network (Bowman and Hodge, 2009). Other promising voluntary approaches being developed and employed by stakeholders have included the risk governance frameworks and risk management systems (see, for example, Hull, 2010; Meili and Widmer, 2010). While these innovative regulatory schemes vary in their focus, structure, and institutional arrangements, their broad objective is the same: to encourage the responsible and commercially successful development of the technology.

While the effectiveness of these softer regulatory approaches will not be known for some time, it is important to note that these voluntary initiatives have not sought to replace the existing state-based regulatory regime in which they operate, but rather supplement them. Such an approach recognises that self-regulation has its own strengths and weaknesses, including a perceived lack of credibility, and that regulatory solutions, including those required for different dimensions of nanotechnologies, will generally require a multi-dimensional approach (Gunningham and Sinclair, 1999). Even at this early stage it is reasonable foreseeable that the challenges posed by nanotechnologies will promote intensive regulatory innovation, under which stakeholders will devise new forms of regulatory approaches to supplement traditional 'command and control' regulations.

Inevitably, the precautionary principle rears its head when one discusses the scope of risk analysis (particularly, risk management), in the EU. It is no secret that the EU, perhaps more than other jurisdictions, subscribes to the precautionary principle. Indeed it is included as one of the core principles of the EU's environmental policy. The EC Treaty itself does not define the principle, and the European Court of Justice typically takes guidance from international environmental law, and from the Commission's Communication on the precautionary principle when called upon to apply it. The 2000 Communication (COM(2000)1) is the highest-profile exercise so far to try and translate the principle into specific guidelines. Importantly, the Communication was initially sponsored by the trade directorate-general at the EC. Sir (now Lord) Brittan, the then trade Commissioner, launched the Communication as a handbook for the use of the principle in EU risk analysis with a view to reassuring the Union's trade partners that recourse to the principle was not haphazard,

unpredictable and therefore, arguably, a violation of international trade agreements, but rather, well thought-through and systematic.

The Commission insists in this document that the precautionary principle in its European context is a justified part of risk management. The latter, the Commission insists, is not a purely scientific exercise but to a considerable degree a policy process. The communication details that any measures taken on the basis of the principle have to be proportionate *vis-à-vis* the level of environmental protection sought; that they must not be discriminatory in their application (in particular *vis-à-vis* the trading partners of the EC); that they are to be consistent with any measures that have already been taken (consistency); that they are to be based on technical analysis and, where possible, economic cost and benefit analysis; and that they are to be subject to constant monitoring and evaluation, including potential review (in particular with a view to integrating potential new scientific developments).
Commission (and, by extension, EU) policy on the precautionary principle by no means represents a 'when in doubt, opt out' approach. In other words , the principle as applied by the EU does not advocate a green light for technologies only where full scientific evidence either testifies to their safety or maps the specific precautions that need to be taken to contain any hazards coinciding with the technology. Hence complete moratoria for a technology, such as advocated by some for the nanotechnology sector, does not immediately fit within the European precautionary approach. However measured precautionary responses for specific applications, e.g. those that have already entered the market-place, would not seem completely untoward; that the Commission has so far not reacted to the distinct possibility of insoluble nanoparticles used in cosmetics penetrating the stratum corneum, passing into the viable epidermis and entering the vascular system, where its consequences are unknown but somehow not unimaginable is in fact testimony to the reluctance of the European institutions to call upon the precautionary principle in the nanotechnology area. With its recent moves on cosmetics, the European Parliament for one is keener to take the precautionary principle to what in all likelihood is a logical conclusion.

11.5. Trust Me, I'm a Regulator

Having analysed the existing EU regulatory frameworks in three specific areas, and having noted that while each framework applies uniformly to products containing nanomaterials as well as conventional products, there are nonetheless some gaps within each of the regimes when dealing with nanotechnologies. This is in part due to the knowledge

gaps associated with potential risks, as well as the composition of the regimes themselves. While this is an important finding, a theoretical examination of the regulatory frameworks and their applicability to nanotechnologies is not in itself enough to decide whether or not the frameworks are adequate for dealing with nanotechnologies. The next step of the authors' project is to therefore to assess the precise impact of the most relevant benchmark criteria that arguably will decide whether the existing frameworks are in fact adequate for regulating nanotechnology-based cosmetics, food and FCMs, and medical applications. This in turn will feed into our development of a regulatory model for nanotechnologies as a whole.

The starting point for this part of the project has been a literature review to determine the most relevant benchmarking criteria for nanotechnologies. These are, (a) the requirements imposed by modern environmental and consumer protection law on the regulation of new technologies; (b) public participation principles of international and EU environmental law as exemplified by the Aarhus process, public participation and other such exercises; (c) the integral approach to regulation, avoiding black holes or what the EU calls a 'regulatory apartheid';[19] (d) the application of international trade law in particular World Trade Organisation law; and (e) the ambitions of regulatory innovation i.e. to devise new forms of regulation as an alternative to traditional ones.

After undertaking an analysis of these principles at the international and European level, the research team will formulate the operational legal boundaries that will subsequently determine the development of a regulatory framework or frameworks for nanotechnologies.

Since the commencement of this project there has been one glaring development. Reviews such as the one in this paper have gained extra relevance given the insistence of regulators worldwide that all was hunky-dory in the nano-regulatory world. With regulatory regimes containing generic duty of care provisions requiring manufacturers in general terms not to put anything 'unsafe' on the market, regulators had insisted for a long time that 'all was covered'. Regulators were in other words requesting from consumers a high level of trust, which in the EU especially (see van Calster, 2008) was received sceptically by consumers and the European Parliament alike. It was not until the European Parliament, as noted above, called for the introduction of specific provisions for nanotechnology in the food and cosmetics

[19] This refers to the phenomenon whereby for a variety of reasons, regulation ends up being lax in certain jurisdictions and strict in others, effectively making consumers in some countries subject to far less protective regimes than their counterparts in other States.

regulations, that the European Commission changed tack and acknowledged that more nano-specific regulation is necessary. It is as yet unclear whether that change of mind will be followed by other regulators.

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Chapter 12. How Biological Science Got the Upper Hand in the Debate on Human Animal Hybrid Embryos in the UK

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Abstract
The UK Human Fertilisation and Embryology Act (HFE Act) can be viewed as a good example of a piece of regulation in which the ideas of a communicative approach to legislation were put into practice. The central claim of the communicative approach is that by according communication processes a central position in the application of general legislative rules, a plurality of perspectives can be integrated into these processes and the rules that result from them. In this chapter, I counter the central claim of the communicative approach by showing how the integration of different perspectives on the issue of the creation of human animal hybrids is obstructed by the working of power in the communication process.

12.1. Introduction[1]

The issue of the creation of human animal hybrid embryos presents a good example for showing what happens to the different scientific and societal perspectives about an issue in the process of formulating legislative rules. In the United Kingdom, the HFE Act gives the HFE Authority the power to decide on a case-by-case if the use and/or creation of human embryos younger than 14 days are desirable and necessary for one or more of the purposes of the Act. In November 2006 scientists submitted applications containing their wish to produce human animal hybrid embryos by using human cells and animal eggs in order to obtain stem cells. The isolation of embryonic stem cells is thought of as a technique that is very promising for the improvement of human health. With these stem cells, scientists expect, for example, to understand much more about the origin of cancer and to develop tissue therapies. Unlike most issues of such high technological character, this became an issue of public debate. Journalists, for instance, reported about the research plans of scientists using alarming headlines about 'Frankenbunnies', because rabbit eggs would be used. This paper will consider what happened to the different perspectives

[1] The debate concerning the creation of human animal hybrid embryos has been used earlier as a case study in N. Zeegers, 'Distinguishing true from other hybrids. A case study of the merits and pitfalls of devolved regulation in the UK', 3(2) *Legisprudence* (2009), 299-321.

brought forward in the debate in the course of the communication processes that led to the revision of the 1990 HFE Act and the enactment of 2008 HFE Act.

12.2. Biomedical Technologies and the Communicative Approach to Legislation

The regulation of biomedical technology brings with it specific challenges for legislators. Firstly, specialized expertise is required to grasp all the relevant aspects involved in technological developments. A second reason is the high pace at which biomedical technology develops and is developing, constantly opening up new possibilities. Thirdly, there is no widespread agreement on the fundamental ethical issues involved. This becomes clear by looking at the equivocal conceptual basis for the status of the human embryo.[2] Finally, the interaction between the pace of scientific and technological development and the way in which the political community 'chooses' to interpret moral principles and ideas. Changes in technological possibilities provoke alterations to the underlying social acceptance.[3]
A means of addressing these issues is the delegation of regulatory power to a committee of experts in different fields of knowledge, such as medicine, science, law and religion. This technique is advocated by the communicative approach in Legal Theory as the means to reconcile flexibility, needed to face the challenges, and certainty, as requirement for legal rules.[4] A key idea of the prescriptive aspect of the communicative approach is that the tensions resulting from these two

[2] In the United Kingdom, as well as in the Netherlands, the law is grounded on the idea of intrinsic worth because of the potentiality of the embryo to grow into a human being and the idea that protection should increase as the embryo develops, because of the growing probability that it will become a human being. Fourteen days after conception is considered a significant moment in legislation. Although based on biological facts of the development of the embryo in the womb, the decision of legislators to take this moment as decisive rather than other moments in the development moral relevant is not uncontested (Lee and Morgan, 2001: 68-72).

[3] To illustrate this, consider the successful creation of induced 'Pluripotent Cells' by researchers at the end of 2007. These cells, created from human adult somatic cells, are very similar to embryonic stem cells. Human embryos or human egg cells are no longer needed to obtain pluripotent stem cells and that is presented as a major moral advantage of this development. But is this consistent with the potentiality argument? If every somatic cell is potentially an embryo the potentiality argument would mean that every somatic cell has some moral status. In that case, the ethical rules for human embryos would also apply to somatic cells (see for a counterargument Holm, 2008).

[4] Dutch advocates of a communicative approach can be found in Witteveen and Van Klink (1999), Zeegers, Witteveen and Van Klink (2005) and Van der Burg (2001). Other advocates are the Australian legal scholar Gunningham (1998) and the British legal scholar Black (1998).

requirements and the challenges of biomedical technology mentioned above can be resolved by deciding on a case-by-case basis on the individuals circumstances in which research is to be authorised. By charging a committee with this task, government can provide rules that leave room for various interpretations and can thus anticipate future possibilities that cannot be foreseen at the time the Act becomes effective. For example, simply forbidding the use of human embryos for research or the creation of human animal hybrid embryos would preclude the technique even in a case where only one such embryo was to be used or created in order to save the lives of million patients. An alternative for legislators is to opt for a rule that allows for the creation of human embryos only where a devolved authority authorises such actions. Under the HFE Act, the HFE Authority is given the power to decide on a case-by-case if the use and/or creation of these embryos are desirable and necessary. The advantage of this rule is that it leaves room for flexibility.

However, this kind of delegation of legislative tasks gives rise to concerns regarding the democratic legitimacy and the acceptability of the specific rules that result. Such rules get their final meaning thus not in a parliament but in a forum that lacks the electoral base of a parliament. Defenders of the communicative approach counter by claiming that as many claims and interests as possible must be included in these processes and in the preceding phases of policy formulation. Their expectation is that, in the end, communication processes such as those provided for in the HFE Act can integrate a plurality of perspectives on the issue at hand. But such integration requires that the legislature ensures that different perspectives are recognised and that no one voice dominates the others.

In practice, however, it is inevitable that some stakeholders will not be (equally) included in the communication processes. Even more important with respect to the question of this broader research project is that the inclusion of different perspectives in communication processes does not automatically lead to the required balancing of the perspectives and the integration into the resulting rules. There are two reasons why integration of different perspectives is not expected to result from these processes. Firstly, the agreement made by expert committees like the Central Committee on Research involving Human Subjects or the HFE Authority is not necessarily based on consensus but can also be based on compromise. The second reason why integration is hampered is power imbalance. The role influence and power play in communication processes is left out in the mainstream of the communicative approach (Zeegers, 2003).The participants in the communication processes concerning the ethical boundaries of

research with human embryos will try to convince each other that their categorization of techniques and their interpretation of the general legislative rule is the right one. In other words, they will try to exert influence on each other's understanding of the facts and the meaning of the values involved.

In sociologist Lukes' (1974; 2005) taxonomy of different forms of power, influence is seen as a form of power whenever conflicting interests are involved. There are many interests involved in research with human embryos that can possibly conflict with each other: the interests of patients who hope that by means of this research a cure can be found for their disease can conflict with the interests of women whose ova are needed to create human embryos with alternative techniques; the commercial interest of the pharmaceutical industry in the cure can conflict with the interests of people that consider the embryo as a person from the moment of creation. One can deduce from this that power is clearly involved in the communication processes concerning the use of human embryos in research. But what kind of power and how can the working of power be analysed?

12.3. Power in Communicative Regulation

Socio-legal scholar Julia Black, an adherent of the communicative approach, is exceptional in acknowledging that the exertion of power is involved in communication processes that are part of regulatory processes on new biotechnological developments (Black, 2002; 1998). Black (1998) distinguishes three dimensions in the communication processes involved in the debates on ethical rules concerning new technologies that can be helpful in analyzing the working of power in the communication processes concerning the legal boundaries of the use of embryos in research: a) the structural dimension that concerns who has access to the decision making processes and to what extent; b) the cognitive dimension, consisting of the perceptions of the participants, their world view, rationalities and operating logics; and c) the communicative dimension, which is concerned with what happens to (cognitive) differences in conceptualizing, categorization and ways of justifying in the process of translation in the subsequent stages of the decision making process.

The role of the structural dimension – which actors have access to the process – in the exertion of influence and power is common knowledge amongst the proponents of the communicative approach, as well as other scholars in legal theory. However, the communicative approach's concern with the inclusion of a plurality of perspectives in communication restricts itself to this structural dimension of

communication. With the other two dimensions of communication, the cognitive and the communicative dimension, attention is drawn to aspects of exerting influence that are less well understood. In order to analyze the working of influence and power in the communication processes concerning the creation of new forms of embryo in all of its aspects, I will focus on the cognitive and communicative dimensions here.

What perspectives does the cognitive dimension of the communication processes concerning the issue of the creation of human animal hybrid embryos consist in? This question will be answered in detail in section 5 and 6, in which an analysis of the politico-legal debate on this issue is presented. In short, the different cognitive perspectives include the legal perspective, referring to the rules in the HFE Act; the scientific perspectives, referring to the biological facts involved; and ethical perspectives, referring to boundaries to be drawn on moral grounds. A relevant ethical perspective is, for example, that in which the mixture of human and animal material is surrounded by taboos. Van Beers (2009) discerned this perspective, termed by her the human dignity perspective, from the Dutch and French legislation concerning the use of human embryos in research, specifically from the prohibition of reproductive cloning and of mixing human and animal material in embryos.[5]

The key elements of this perspective are: 1) An absolute boundary between animal and human beings; 2) Man cannot be reduced to a commodity or an instrument; and 3) Man is a unique and free creature.[6]

What purpose would be served by drawing out the communicative dimension of the communication processes alluded to above? Following Black, I will draw attention to what happens to the differences between these cognitive perspectives in the course of communication processes as part of regulation. The fact that these

[5] In The Convention on Human Rights and Biomedicine human dignity is the central principle. However, it is still a rather hollow and non-committal principle that is to be given content in positive law. This principle of human dignity is different from the principle of respect for the unborn human being, the latter being what guides the legal status of the embryo as (potential) human being (Van Beers, 2009: 223).

[6] According to Van Beers, the human being that is to be protected by the principle of human dignity is not the human being as absolute, factual category but as contextual, anthropological category (2009: 576). As the unveiling of the human genome has conveyed, a human being is not unique in terms of its genetic constitution as it is not much different from animal primates. Therefore the protection of human dignity can no longer be based on scientific facts but must be based on collective meanings, according to Van Beers. In other words, discussions about the regulation of medical biotechnology are not so much about human bodies, organs, embryos and corpses but about what their symbolic value is to us as a community.

perspectives have different languages places a barrier on communication. The communicative dimension is concerned with what happens to these differences in the subsequent stages of the decision making process. These differences can either be bridged, for instance by conceptual integration, or one perspective can prevail at the expense of the other. In the latter, the working of negative power, in the sense of the exclusion of perspectives from the deliberation, can be identified, whereas in the former, the power is positive in the sense of producing new forms of knowledge, meanings and practices.[7]

Van Beers, for example, considers the human dignity perspective as being placed under ever more pressure by the possibilities that biomedical technologies offer or at least promise. Taking notice of the debate on the issue of the creation of human animal hybrid embryos in the UK and considering the perseverance of other taboos concerning birth and death, it indeed is remarkable how easy the taboo surrounding the mixture of human and animal genetic material was side-stepped and how fast legislative bans have been lifted. Although traces of the human dignity perspective were present in the public debate, this perspective seemed to be absent at the moment the HFE Act was enacted. In the following section, I will describe the processes of communication concerning the rules for the creation of new forms of embryo in this new Act and the differences between the human dignity perspective and a scientific perspective.

12.4. Introduction of the Issue of the Creation of Human Animal Hybrid Embryos

The issue of 'human-animal hybrids' was first put on the political agenda in the UK by the Select Science and Technology Committee in 2005.[8] This Select Committee is charged with monitoring the work and activities of the Office of Science and Innovation, which is part of the Department of Trade and Industry.[9] In 2005, this committee recommended to Parliament making the creation of human-animal

[7] This concept of power as productive is derived form Foucault (1976) 'Twee typen macht. College van 4 januari 1976', 25(3) *Te elfder ure*, 573- 585.

[8] In fact the debate was not only concerning the creation of human-animal hybrid embryos but also on human-animal chimeras. For reasons of clarity I will restrict the focus of this paper to the first category of human-animal embryos.

[9] The Select Committee Science and Technology Committee is one of 18 departmental select committees in the House of Commons charged with monitoring the work and activities of a specific Government department. The Science and Technology Committee is unusual in that it monitors the Office of Science and Innovation, which is part of the Department of Trade and Industry, rather than a department in its own right. The Select Committee Science and Technology is made up of around 10 to 15 MPs.

chimera or hybrid embryos possible.[10] The Department of Health next brought up the issue in September 2005, when it informed the HFE Authority that this issue would be considered as part of the review of the 1990 HFE Act.

In November 2006, the HFE Authority received two applications from scientific teams requesting permission to carry out research using human cells and animal eggs to produce stem cells.[11] The HFE Authority is central in the framework for control of embryo research in the UK. The HFE Authority is a statutory body, created in 1991 under the Human Fertilization and Embryology Act (1990).[12] The Authority is responsible for licensing the creation, storage and use of human embryos for research.[13] In order to get the approval of the HFE Authority, researchers who wish to use spare embryos in their research must submit a research protocol that makes clear that the research is 'necessary or desirable' for one or more of the purposes of the HFE Act.[14] In addition to being convinced on the research being either

[10] House of Commons Science and Technology Committee, *Human Reproductive Technology and the Law* (Eighth Special Report, March 2005). In this report the Science &Technology Committee recommended that new legislation was required inter alia to make the creation of inter-species embryos legal for research purposes subject to the 14-day rule and the prohibition on implantation in a woman. In addition, the new legislation was required to define the nature of interspecies embryos.

[11] The scientists responsible for the applications wanted to produce stem cells using human cells and animal eggs; because the mitochondria from the donor egg are still present, the resulting embryo contains nuclear DNA from the human cell and mitochondrial DNA from the animal egg. This means that the resulting embryo would contain a small amount of animal DNA from the mitochondria present in the animal egg (less than 1%). The applicants for a license were Dr. Lyle Armstrong, Institute of Human Genetics, University of New Castle and Dr. Stephen Minger, Stem Cell Biology Laboratory, Wolfson Centre for Age-Related Diseases, King's College London.

[12] The primary remit of the HFE Act is to license and monitor UK clinics that offer IVF (in vitro fertilisation) and DI (donor insemination) treatments, and all UK-based research into human embryos. The authority also regulates the storage of eggs, sperm and embryos.

[13] The HFE Act stipulates that the composition of the Authority be 21 members chosen to bring to their office a broad range of medical, scientific, social, legal and religious knowledge and experience. There are several other provisions in the HFE Act concerning the composition of the Authority: the Secretary of State shall make appointments and has to ensure that the Authority must be informed by the views of both men and women. At least a third but not more than half of the membership has to consist of persons with a background as medical practitioner, human embryo research or the commissioning, funding of or decision making on this research. Persons belonging to these categories are disqualified from being appointed as chairman or deputy chairman in order to ensure that the overall direction of the authority is independent of the medical-scientific view (Lee and Morgan, 2002: 102-103).

[14] Desirable is assessed in terms of the contribution to scientific knowledge or human health that can be expected from the research. Necessary means that creating such embryos (instead of using other sources of stem cells) is necessary for the research.

necessary or desirable, the Authority cannot issue a license unless it is satisfied that the use of an embryos is necessary for the research (sch. 2, para. 3 (2) and (6)) (Lee and Morgan, 2001: 120).

Before the Authority was able to take the applications for research using human cells and animal eggs into consideration it needed to know whether, according to the HFE Act 1990, the embryos that would be created in this research would fall under their remit. The definition of the human embryo in this act stipulated that such embryo must have 'a full human genome' and 'be alive'. The definitions of these categories appeared to be contested even among scientific experts. This turned the question of whether the creation of human-animal hybrid embryos should be allowed into a 'legal boundary conflict' with respect to the HFE Act 1990. It is therefore necessary to analyse the politico-legal debate preceding the decision making of the Authority. The subsequent section, section 6, will then consider the politico-legal struggle over the amendment of the HFE Act 1990 in the legislative arena.

12.5. The Decision-making Process by the HFE Authority

The HFE Authority first had to address the question of whether the forms of embryo that would result from the research in the application would contain a 'full human genome' and 'be alive'. Two committees of this authority had already been involved in answering questions from the Department of Health concerning human animal hybrids: the Scientific and Clinical Advances Group (SCAG)[15] concerning the scientific aspects and the Ethics and Law Committee (ELC) in regard to the ethical aspects of the creation of these forms of embryo. The SCAG considered that any embryo with a human genome falls under the remit of the HFE Act. The proportion of human derived and rabbit derived proteins should be taken into account when deciding whether these hybrid embryos should be classed as human. The SCAG was asked to review the role that mitochondrial DNA plays in the development of the embryos and whether embryos containing human DNA and both human and animal mitochondrial DNA could be considered a human embryo. In May 2006 both the SCAG and ELC agreed that the hybrids should be regarded as an 'embryo' for the purposes of the Act 1990. They also agreed that the creation, keeping or use of such an embryo in principle could be regarded as necessary or desirable. The ELC concluded from this that a license committee of the HFE Authority

[15] This is a group of scientific experts that advises the Authority on questions concerning new scientific and clinical developments.

'would have the discretion to authorize these activities in the case of application'.

However, in the meantime, scientists had publicly stated their wish to create these hybrid embryos by fusing human cells with rabbit cells, and newspapers had written about these plans. Some public unease with these scientific experiments was expressed. For the Government, which was in the process of writing proposals for amending the HFE Act, this public unease was reason to make a statement about hybrid and chimera embryos in its White Paper: 'The government will propose that the creation of hybrid and chimera embryos in vitro, should not be allowed' (White Paper, December, 2006). Apparently, the Government at that point considered the combination of human and animal material in an embryo a bridge too far.[16]

This statement of the government did not fail to impact on the HFE Authority. With the government proposal for a ban on the creation of hybrid embryos, the Authority was no longer certain about its case and sought legal advise concerning the question of whether this research was covered by the legal meaning of embryos under the HFE Act 1990 and therefore fell under its remit. The HFEA's Horizon Scanning Expert Panel (HHSEP) was also asked to advise.[17] The respondents agreed that the hybrid embryo would contain a complete human genome. However, there was no consensus on whether a hybrid embryo would be capable of implantation. Legal advice subsequently informed the Authority that 'if the embryo contains a complete human genome and it cannot be shown definitively that the embryo does not have the normal potential to develop, it is most likely that the court would find that this constitutes a live human embryo for the purposes of the Act'.[18]

On 11 January 2007, the Authority ruled that, under current regulation, the research did indeed fall under their remit. However, it postponed the actual decision about the applications in order to first have a 'full and proper public debate and consultation as to whether in

[16] Although the government in the same paper proposed that the law contains the power to enable regulations to set out circumstances in which the creation of hybrid and chimera embryos *in vitro* may in future be allowed under license for research purposes only (White Paper, December 2006).

[17] The HHSEP is a worldwide panel of experts. The panel includes experts in stem cell technology from universities in the UK, Australia and Japan, specialists in assisted reproductive technologies from the US and Belgium and leading academics in cloning techniques, developmental genetics and cryopreservation.

[18] The legal advice was provided by a body termed the 'Council'. Here the Council is referring to the purposive approach to statutory interpretation used by the House of Lords in the Quintavalle case of 2003 in order to interpret the 1990 Act. The Council's reason for regarding the embryos as falling under the remit of the Authority was that the courts would be likely to see the embryo in a way that ensures that this type of research falls under the scope of regulation rather than not.

principle, licenses for these sorts of research could be granted'.[19] Apparently, the Authority felt the urge to organise a public consultation itself, as the government had been sufficiently moved by 'the public unease' to propose banning the creation of hybrid embryos.

In the public consultation, the HFE Authority sought the views of the public, interest groups and the scientific community.[20] The consultation document distinguished between three types of human-animal hybrid embryos and two of these three were juxtaposed as the true hybrid and the 'cytoplasmic hybrid'.[21] These two types were presented as follows:

> The category of 'hybrid embryo', also called 'true hybrid' contains embryos which are created by mixing human sperm and animal eggs or human eggs and animal sperm. This is what people think of when they think of hybrids: "they don't think of cytoplasmic hybrid embryos created in stem cell research, instead they imagine the half-human, half-animal monsters, like the minotaur that are associated with myths and legends". However the only two species that are genetically similar enough to produce life are mules and hinneys. True hybrid embryos might possibly be created in the laboratory but "any attempt to create a living hybrid from two closely related species would be extremely unlikely to even produce a viable pregnancy".[22]

The document continued: "These embryos would be different from 'cytoplasmic hybrid embryos' in that they would have an equal amount of DNA from the two species from which the eggs and the sperm are obtained".[23] The 'cytoplasmic hybrid embryo' is created by combining a human nucleus with an enucleated animal egg and would contain less than 1% animal DNA. In other words, this document attempts to reassure concerned respondents by juxtaposing the image of the Minotaur to the following schematic presentation of the cell nuclear replacement that will be applied in the submitted research proposals.

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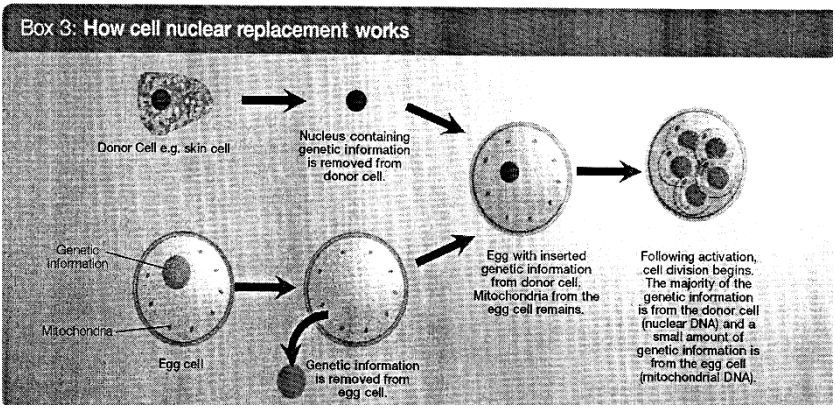
[19] See www.hfea.gov.uk (accessed 26 February 2010).

[20] The aim of the consultation was "to consider this kind of research in the broad context of embryonic stem cell research". See HFE Authority, *Hybrids and Chimeras* (April 2007: 6).

[21] The third type that fell within the category of 'hybrids' is the transgenic human embryo: forms of human embryo that have animal genes inserted into them during early development. Such embryos have not yet been created, although transgenic animal embryos have.

[22] HFE Authority, 2007, 9.

[23] *Ibid.*



(Source: HFE Authority, April, 2007: 8)

In addition the Authority underscored the difference between 'cytoplasmic hybrid embryos' and 'true hybrids' by highlighting the amount of animal DNA the former would contain. The description of 'cytoplasmic hybrid embryos' as containing maximum 1% animal DNA was subsequently used in an opinion poll concerning the use of embryos in research and 48% disagreed with the creation of such an embryo while over a third of those polled supported it.[24]

On 5 September 2007, the HFE Authority published a statement on its decision regarding hybrid embryos. The statement noted: 'public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and it is likely to lead to scientific or medical advancements'. By calling public opinion 'divided' the Authority refers to the outcome of the opinion poll that 48 % of the respondents was against the creation of 'cytoplasmic hybrid embryos'. The claim that these respondents would withdraw their objection in cases where 'the research would be tightly regulated' is derived from the 'public dialogue work' that was also part of the consultation, and in which various public perceptions, motivations and attitudes to the creation of human-animal embryos were explored.[25] The Authority combined this conclusion and the contribution of scientists to the consultation with the former legal advice and concluded that

[24] In July 2007, a sample of 2073 residents of the UK was interviewed.

[25] This public dialogue work consisted in meetings and workshops in which various public perceptions, motivations and attitudes to the creation of human-animal embryos were explored (HFE Authority, 2007: Section 4).

'cytoplasmic hybrid embryos' as specific form of hybrid and chimera research could be permitted.[26]

At the point at which the HFE Authority took its decision, the scientific experts that had been involved in the process of decision making had found common ground with lay persons, at least those consulted, in the combination of the acceptance of the creation of 'cytoplasmic hybrid embryos' with the rejection of 'true hybrids'. The following quantitative criterion of scientists had proven to be successful in convincing part of those opposed to human-animal hybrid embryos in this arena: forms of human-animal hybrids with 50% or more animal derived DNA were held to unacceptable in contrast to forms with 1 % or less animal derived DNA. By making this distinction, the Authority appeared to acknowledge, at least to some extent, the human dignity perspective in which the boundary between animal and human beings is meaningful. This perspective had been given voice by the media; and the HFE Authority showed itself to be responsive to the revulsion generated by mixing human and animal material expressed by them.

However, the responses the scientists of the Horizontal Scanning Expert Panel gave in the public consultation raises questions about the quantitative criterion presented above. This criterion is based on what kind of DNA is put together in the test tube in the initial phase of the process of the creation of the entity. By focusing on the ingredients that are initially put together, and the specific proportion of human and animal material in these ingredients, the essence of embryonic development seems to be missed. According to the scientists of the Horizontal Scanning Expert Panel, the mixing of the material activates processes that produce new material that is neither human nor animal to the same extent as the initial mix. Their general view was that 'at some stage after embryonic genome activation all proteins produced (with the exception of those coded by the animal mitochondrial genes) would be human'.[27] While the embryo relies on proteins and genetic messages present in the oocyte from the animal up to the fourth cell stage, this changes with the genome activation that takes place in cell stages four through to eight. After this genome activation, the stem cells formed would be almost entirely human. Thus, from these latter cell stages until the blastocyst stage (the point at which the stem cells are derived), the entity could be considered as human, according to the

[26] In reference to other kinds of human hybrid and human chimera research, the statement provided that 'not only did the scientific community not wish to perform such research at present but also (...) the prospect was so distant that they could not envisage what forms this research would take in future' (HFEA Statement, 5 September 2007).

[27] HFE Authority, *Hybrids and Chimeras*, October 2007, Appendix H, section 6.

international scientific experts consulted by the HFE Authority.[28] While the quantitative criterion above is based on whether genetic material is derived from an animal or a human being, this information makes clear that the degree of either human or animal material in the early embryo changes with the stages of development the creature goes through.

12.6. The (Pre)-Legislative Process of Amending the 1990 HFE Act

By the beginning of 2007, a lobby of scientists and Members of Parliament were trying to convince the members of the Authority, and the public more generally, that the creation of hybrid embryos should be permitted. For example, a number of scientists and MPs sent a letter to the members shortly before the Authority was expected to make a decision telling them it would be wise not to listen to the government and to support the research. This letter was published in *The Times*.[29] The letter was signed by scientists involved in stem cell research, such as Stephen Minger, Lyle Armstrong and Ian Wilmut and several members of the Select Committee Science and Technology, such as Liberal Democrat MP Evan Harris.[30]

In April 2007, the Select Committee Science and Technology published its inquiry into the government's proposals for the new legislation for the use of embryos for research.[31] This inquiry consisted, *inter alia*, in three oral evidence sessions during which the Select Committee Science and Technology heard stem cell scientists as well as government officials, ethicists, a bishop and a leader of the organisation Human Genetics Alert.[32] According to the Select Committee, there was a need to allow research using human-animal chimera and hybrids to proceed immediately. The Committee conceived the proposed ban on the creation of these embryos by the government as at odds with their own recommendations in the last parliament.[33] It used the specific example of 'cytoplasmic hybrid

[28] The blastocyst stage is preceded by the morula stage, a 16-32 cell stage.

[29] *The Times*, 10 January 2007. On January 11, the Authority declared it would postpone the actual decision. The letter in *The Times* was also signed by other scientists, Nobel laureates amongst them, as well as social scientists, legal academics, medical ethicists and leaders of organisations of medical professional organisations and organisations of bio industry and bio science.

[30] Stephen Minger and Lyle Armstrong were the applicants for the license to create human animal hybrids.

[31] House of Commons Science and Technology Committee, *Government proposals for the regulation of hybrid and chimera embryos*. Fifth Report, 5 April, 2007.

[32] *Ibid*., 7.

[33] See House of Commons Science and Technology Committee, *Human Reproductive Technology and the Law* (Eighth Special Report, 2005).

embryos' to argue why such research was desirable and necessary.[34] Scientific aims that would make the creation of human-animal chimera or hybrid embryos necessary were the pursuit of knowledge about the genetic basis of disease and the direction of stem cells into future cell-based therapy. The stem cells produced would be medical useful in drug discovery and toxicity testing (2007: 61). The committees' assessment of the use of embryos in research was thus mainly focused on the creation of 'cytoplasmic hybrid embryos'. However, its conclusion was that the creation of all interspecies embryos should be allowed.

The committee put the distinction between different subcategories of embryos in terms of degrees of 'humanness' into perspective. They pointed to the similarity between humans and non-human primates and other animals: 'In scientific terms, how human an entity is could perhaps be described through determination of its percentage of human genetic material. Scientists have shown that humans are 96 per cent similar to chimpanzees, whilst genetic similarity between humans and rabbits (...) is around 80%' (2007: 23). What the Select Committee is clearly doing with such a statement is bringing biological facts into position against the human dignity perspective that the HFE Authority in its public consultation had taken into account.

In their inquiry, the committee started by considering what name should be chosen 'for what would result from the proposals to create embryos through somatic cell nuclear transfer of human genetic material into animal ova from which the main source of genetic material has been previously removed'.[35] Various names given by scientists were considered: Professor Shaw of King's college called them 'pseudo-hybrids', Dr Lyle Armstrong of Newcastle University 'interspecies embryos' and Professor Austin Smith of the University of Cambridge thought they would be better termed as 'cybrids'. Professor Sir David King argued that the entities that the scientists wanted to create 'should not be described as either chimeras or hybrids'.[36] He proposed calling them 'cytoplasmic hybrid embryos', which seems not a little contradictory to the desire to avoid calling them hybrid. The Science and Technology Committee decided to use Sir David King's

[34] This is the form of the embryo the scientists proposed to create. The committee described this category as 'what would result from the proposals to create embryos through somatic cell nuclear transfer of human genetic material into animal ova from which the main source of genetic material has been previously removed'. House of Commons Science and Technology Committee, *Government proposals for the regulation of hybrid and chimera embryos* (Fifth Report, 5 April 2007), 6.

[35] *Ibid.*

[36] Sir David King was the UK Government Chief Scientific Adviser and Head of the Government Office for Science from October 2000 to December 2007.

description in the remainder of the report, without giving reasons for this choice.

The government followed the recommendation of the Select Committee to the extent that this was congruent with the line of reasoning of the HFE Authority: in its draft Bill, it proposed to include the creation of 'cytoplasmic hybrids' in the categories of embryo that may be authorised by a research license by the HFE Authority.[37] However, in contradiction to the recommendation of the Select Committee the government in the draft Bill proposed to forbid the creation of 'true hybrids'.[38] In the introduction to the draft Bill, the Secretary of State for Health noted concerning the list of forms of embryo that would be conditionally allowed: 'This list (...) does not include 'true' hybrids created from mixing human and animal gametes (...) other than as currently permitted for the purpose of testing the fertility or normality of human sperm'.[39]

In the Summer of 2007 an inquiry into the draft bill was made by the Joint Committee on the Human Tissue and Embryos (Draft) Bill.[40] The Joint Committee on the Human Tissue and Embryos (Draft) Bill was

[37] The 'types of embryos created by combining together human and animal gametes or human embryos altered using animal DNA or animal cells' were named 'interspecies embryos'. In this draft bill, the interspecies embryos were to be explicitly excluded from the definition of an 'embryo'. Instead these forms of embryo were to be regulated under a new section 4A with the title Prohibitions in connection with genetic material not of human origin. The "cytoplasmic hybrids" fall under the description given in (b) of the following forms of interspecies embryo that were distinguished in this draft bill:
(a) an embryo created by using human gametes and the gametes of an animal,
(b) an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell,
(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal,
(d) a human embryo that has been altered by the introduction of one or more animal cells, or
(e) any other embryo that contains both –
(i) any haploid set of human chromosomes, and
(ii) any haploid set of animal chromosomes of any other sequence of nuclear or mitochondrial DNA of an animal. See Human Tissue and Embryos (Draft) Bill, May 2007.

[38] A way out of this ban was built into the proposal by stating that permission could be made possible by regulations made by the Secretary of State, see Human Tissue and Embryos (Draft) Bill, May 2007, x.

[39] The Hamster test as well as the creation of (other) true hybrids would fall under the form of embryo as described in footnote 37 under (a) but is banned from being conditionally allowed by the statement of the Secretary of State. See Human Tissue and Embryos (Draft) Bill, May 2007, ix-x.

[40] Joint Committee on the Human Tissue and Embryos (Draft) Bill, Human Tissue and Embryos (Draft) Bill, vol. I: Report, HC (2006-07) 630-I, HL Paper 169-I; Joint Committee on the Human Tissue and Embryos (Draft) Bill, Human Tissue and Embryos (Draft) Bill, vol. II: Evidence, HC (2006-07), 630-II, HL Paper 169-II.

established by the House of Parliament in order to consider the draft Bill presented by the government in May 2007. The Joint Committee was asked to report to the House by 25 July 2007.[41] The report of the Joint Committee was informed by evidence coming from a handful of stem cell scientists, organisations involved in bioscience and government officials, but also from organisations critical of the use of embryos in research, from religious as well as other backgrounds.[42] The Joint Committee also recommended the inclusion of the 'true hybrid embryo' in the categories that would conditionally be allowed, thus opposing the government's proposal to exclude the category of 'true hybrids'. The Joint Committee reasoned that there was no 'sound point of principle' on which the distinction between true hybrids and the other categories could stand, referring explicitly referred to the ethicist, Søren Holm, who as a witness before the committee had claimed that both categories of hybrid embryos were 'equally objectionable on ethical grounds'. Once researchers have crossed the species barrier, no valid distinction is to be made between an entity that is 99% human and an entity that is 50% human.[43] According to the Joint Committee, this view was supported by many others, and it referred to the contributions of the All Party Parliamentary Pro-Life Group, Christian Action Research and Education and the Christian Medical Fellowship. In addition, the Committee noted that Vivienne Nathanson, Director of Professional Activities of the British Medical Association, also saw no sense in the distinction.[44] These organisations were against the creation of all subcategories of interspecies embryos and, like Holm, objected to allowing this creation. However, the Joint Committee, by giving a twist to Holm's argument could use it to the advantage of their own purpose, which was to include 'true' hybrids in the permissible category. As the Joint Committee noted, whether it was or not was irrelevant to these organisations anyway.

The Minister of State for Public Health opposed their arguments with the pragmatic argument that there was currently no call for

[41] The membership of the Joint Committee consisted of nine members of the House of Commons and nine members of the House of Lords. Five of the MPs were members of the Science and Society Committee or had been a member of the former Science and Society Committee.

[42] Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol. I, *supra*, Appendix 2. The committee also conducted an online consultation on four questions via its website, two questions related to interspecies research.

[43] Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol. I, 46.

[44] The reason she gave was that bringing the true hybrid under the remit of the HFE Authority would make the rules more flexible and make it easier to allow the creation of true hybrids at the moment that this would become essential. See Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol. II, 49.

research using 'true' hybrids, and given that public opinion was a concern, discussion on this point should be postponed. The Joint Committee was not to be persuaded by this argument and added that 'true' hybrids had already been created in the so-called 'hamster-test'.[45] This is a well established and explicitly endorsed test in which human sperm is mixed with hamster eggs to test the health and motility of human sperm. Government officials sought to explain the difference between the 'true' hybrid resulting from this test and any other sort of 'true' hybrid but their explanation appeared not to persuade the Joint Committee. In its report, the Committee insisted that no distinction should be made.

The Joint Committee also contested the scientific facts on which the quantitative criterion for the distinction between the two forms of embryo was based. In questioning Professor Richard Gardner about the idea that a human genetic constitution of 50 per cent or more is a significant factor in determining whether an interspecies embryo should be defined as human he answered that it depended upon what you are talking about when using the concept of 'genetic constitution of the interspecies embryo': the amount of genes in the mitochondria of the animal cell or the amount of DNA that the mitochondria contribute to the (new) cell.[46] He also noted that it is not possible to be certain about what will happen when cells from two origins are combined: 'one contributed can out-compete the other'. One can conclude from this that the degree of humanness of the resulting entity can not really be established by looking at the amount of human and animal DNA put into it at the beginning of the process. Moreover, it could even be the case that the animal DNA out-competes the human DNA. This option was not accounted for in the reasoning about embryonic development that informed the quantitative criterion that was formulated by the scientists in the HFE Authority.

On 13 November 2008, the 2008 HFE Bill became an Act of Parliament.[47] The name of inter-species embryos that had been given to the human animal forms of embryo in the Bill was changed by an amendment in the House of Lords to 'human admixed embryo'. The 'human admixed embryo' refers to types of embryo that contain both human and animal DNA, and five subcategories of these types are distinguished in section 4A(6). From the Explanatory Notes it becomes

[45] Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol. I., 46.

[46] Gardner continues his argument 'the amount of genes in the mitochondria is about 13 genes compared to 30.000 in the human nucleus genome whereas the total mass of mitochondria and the amount of DNA that they contribute to a cell could be extremely substantial', Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol. II, 207.

[47] Human Fertilisation and Embryology Act 2008 (C22).

clear that the cytoplasmic hybrid embryo (section 4A(6)a) as well as the hybrid embryo (section 4A(6)b) are included in the subcategories of human animal forms of embryo that are conditionally permissible.[48]

12.7. Conclusion

What happened to the differences between the human dignity perspective and the scientific perspective on the issue of the creation of human animal hybrid embryos in the stages preceding the enactment of the HFE Act 2008? The human dignity perspective was brought forward in the public debate, especially in the media coverage of the research proposals concerning the creation of embryos using rabbit eggs. The HFE Authority, at least to some extent, acknowledged the human dignity perspective. Their proposal to allow the creation of 'cytoplasmic hybrids' in distinction to 'true hybrids' can be considered as a compromise in which considerations concerning scientific progress, the promises for human health and economic profit prevailed, but where the human dignity perspective was also taken into consideration. In the legislative arena the government tried to make this distinction legally relevant by proposing in its draft bill to include the creation of the first form of hybrid embryo and exclude the creation of the 'true hybrid embryos' from what would be permissible.

However, it must be noted that distinguishing 'true hybrids' from other types of interspecies or human mixed embryos – the first being entities with a degree of 50% or more of an animal genetic constitution – does not fit easily into the human dignity perspective either. From a human dignity perspective even the smallest amount of animal DNA in a human embryo would be wrong. By making such a principled argument, the human dignity approach was put aside as irrelevant. The scientific perspective put the boundary between humans and animals into perspective by pointing to the extent to which human and animal genes are the same, 80% in the case of rabbits. Such a perspective raises no barriers to the mixing of human and animal material and easily prevailed in the legislative stages of the debate on the issue of

[48] See Human Fertilisation and Embryology Act 2008, Section 4A(6):
(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with –
  (i) two human pronuclei, or
  (ii) one nucleus of a human gamete or of any other human cell, or
  (iii) one human gamete or other human cell.
(b) any other human embryo created by using –
  (i) human gametes and animal gametes, or
  (ii) one human pronucleus or one animal pronucleus.

human animal hybrid embryos at the expense of the human dignity perspective.

This analysis shows that the scientific perspective is gaining power in matters concerning biomedical technology, even the part involving human embryos, as if scientific truth is ultimately the only thing that is relevant in such cases. However, ethical restrictions of the way in which human embryos are treated are not based on biological facts but on human conventions. Therefore, we should take moral intuitions more seriously than has been the case in the debate analysed here. This is not to say that we should not reflect on these intuitions: of course we should consider whether these are reasonable and not take them as everlasting truths that cannot change with time and context. But it is to say that we need to reflect on these intuitions as we need to reflect on scientific knowledge. The analysis above shows, for example, that scientific knowledge that at one stage of the decision making process was presented as certain, such as the proportion of human and animal DNA a 'cytoplasmic hybrid embryo' would contain, at another stage appeared to be contested. Both moral considerations and scientific considerations should be given due attention in order to decide what kind of research should be facilitated by law and what kind of research should be prohibited.

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Chapter 13. Regulating Technologies and the Uncertainty Paradox

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Abstract
In Van Asselt and Vos (2005; 2006), we coined the notion "uncertainty paradox", i.e. an umbrella term for situations in which uncertainty is present and acknowledged, but the role of science is framed as one of providing certainty. In instances of the uncertainty paradox, the public, policy-makers and judicial authorities resort to experts for conclusive evidence and definite answers, despite uncertainty precluding both conclusiveness and definitiveness. Hence, on the one hand, it is recognised that science cannot provide decisive evidence on highly uncertain risks while, on the other, policy-makers and judicial authorities increasingly turn to science for certainty. In this paper, we will elaborate on the role of uncertainty in regulating technology. Through a comparison of several case studies on European risk governance, it will become evident that the uncertainty paradox dominates current technology regulation, however, it manifests itself in a different way. Uncertainty intolerance turns out to be important in understanding various manifestations of the uncertainty paradox. This paper will show that in particular cases certain actors involved in risk and technology regulation acknowledge uncertainty, while other actors, the uncertainty intolerant actors, fail to do so.

13.1. Introduction

Uncertainty is a salient feature of societal debates on new technologies. Nowotny et al. (2001) argue convincingly that innovation always produces uncertainty, or even an "ever increasing flow of ever new uncertainties". Uncertainty is an inherent by-product, an "inevitable side-effect" of innovation. Especially in the early decades of new technology, there will always be irresolvable uncertainty because of the novelty of the phenomena. Research on environmental and health risks, and especially on long-term effects, will by definition not keep pace with technological developments. Harremoës (2002) emphasizes the problem of assessing the effects of a new technology when there is a long lag time between exposure and measurable impacts, the so-called "latency lacuna": technology and the conditions in which it is used will have changed by the time such delayed effects become clear. Technology development and dissemination is a dynamic, ongoing process, so often new versions are introduced in rather short time frames. Furthermore, new technology usually evokes new practices,

different patterns of behaviour and changing societal conditions, which may also alter because of other dynamics. So the context in which the technology is used also changes over time.

Furthermore, in the early phases of technological innovation the benefits are strongly emphasized (see e.g. the work of van Lente (1993) and colleagues who study the role of expectations (i.e. stories about the benefits of innovations)). Discussions about risks usually start at a later stage, when the new technology is already being implemented and diffused throughout society. By then, there are vested interests and strong proponents of the technology. This is also summarized in the Collingridge (1980) dilemma of control of technology: attempting to control the technology is difficult because in its early stages, when it can be controlled, not enough is known about its harmful social consequences to warrant control, but by the time consequences are apparent, intervention has become expensive and drastic as the technology is well developed, disseminated and institutionally integrated in society. As technological innovation is so inexorably connected with uncertainty, the challenge is to look beyond traditional risk assessment strategies and investigate how to deal with uncertainty in the regulation of (new) technology.

In Van Asselt and Vos (2005; 2006), we coined the notion of "uncertainty paradox", i.e. an umbrella term for situations in which uncertainty is present and acknowledged but where the role of science is framed as one of providing certainty. In instances of the uncertainty paradox, policy-makers and/or judicial authorities resort to experts for conclusive evidence and definite answers, despite uncertainty precluding both conclusiveness and definitiveness. Hence, on the one hand, it is recognised that science cannot provide decisive evidence on highly uncertain risks, while, on the other, policy-makers and judicial authorities increasingly turn to science for certainty (see also Weingart, 1999 and Rogers, 2003). It is generally agreed that uncertainty is the essence of the precautionary principle. The precautionary principle legitimates decisions and actions in situations characterised by uncertainty (see box 1 for an elaboration and for an overview of the legal literature and case law). In uncertainty paradox-type situations, a very high level of scepticism as to what science can deliver, goes hand in hand with a very optimistic level of confidence regarding what science should be able to deliver (Forrester, 2006).

The uncertainty paradox raises important questions about the role of science, knowledge, scientists and knowledge producers when dealing with uncertain risks in regulating technology. Our analysis of actual cases of EU risk regulation (Van Asselt and Vos, 2006; Van Asselt et al., 2008, and Van Asselt and Vos, 2008) demonstrates that

such an uncertainty paradox results in unproductive and/or unintelligible policy-making processes. Subsequently, questions of responsibility will emerge (compare Mourik, 2004), possibly resulting in situations of what Ulrich Beck has called 'organised irresponsibility' (Beck, 1986). Beck uses the term to refer to a situation that arises for which society is ill-prepared and with which it is inadequately able to deal, such as the inevitable surprises, negative consequences and/or long-term impacts associated with uncertain risks, notwithstanding all institutions and procedures in place and the pretence of certainty and control (Van Asselt and Vos, 2008). Informed by this empirical research on risk regulation practice, we aim to look beyond the manifestation of the uncertainty paradox and identify and examine mechanisms that bring about and sustain this paradox.

In this paper, we will elaborate on the mechanisms leading to the uncertainty paradox in regulating technology by revisiting four case studies. Firstly, the Pfizer case which related to the use of antibiotics as a growth promoter in the production of meat; and secondly the EU GMO cases, which are composed of three cases pertaining to the import of genetically modified organisms. These cases, in one way or another, deal with uncertainty in relation to regulating (new) technology/ the use of technological products. Through a comparison of these case studies on European risk governance (Van Asselt and Vos, 2006; 2008), it will become evident that the uncertainty paradox is dominant in current technology regulation; however, it manifests itself in different ways. The cases serve as useful material to study the mechanisms behind the uncertainty paradox. What do these cases teach us about the mechanisms that bring about and/or sustain the uncertainty paradox? We will show that the uncertainty paradox manifests itself in a different way in the Pfizer case compared to the three GMO cases, and uncertainty intolerance turns out to be an important mechanism that helps to explain this difference in manifestation of the uncertainty paradox.

Box 1. The precautionary principle and the uncertainty paradox.

Acknowledgement of the limits of science in providing conclusive evidence, i.e. the impossibility of full certainty, has led to the development of the precautionary principle, which is laid down as a principle under Article III-233 within the context of European environmental policy. The precautionary principle is inferred when '*there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'* (Rio Declaration, 1992). At the same time, all legal formulations (Fischer, 2002) of the precautionary principle include what is called a 'knowledge condition' (Manson, 2002), i.e. the level of proof needed to trigger application (Petersen and van der Zwaan, 2003). Although this knowledge condition is often kept vague or ambiguously formulated, the point is that such a knowledge condition implies that lawyers and policy-makers appeal to scientists and experts for some kind of 'plausibility proof', namely statements by experts in which their risk judgements are cast as conclusive evidence on the existence or non-existence of an uncertain risk (Van Asselt and Vos, 2008). This request has the tendency to morph into demanding conclusive evidence on whether something is a risk. Such requested certainty about uncertain risks seems highly incompatible if not contradictory to uncertainty as the core of the precautionary principle, which implies that neither definite proof nor evidence is available. In Van Asselt and Vos (2009), we argued that through the knowledge condition, the uncertainty paradox is already part of the precautionary principle. In recent discussions on the precautionary principle its relevance has been underlined (WRR, 2008). Nonetheless, careful application, in the form of a 'second nature' is insisted upon (GR, 2008).

13.2. Uncertain Risks

Prominent risk scholars have made very clear that dealing with uncertain risks is a key challenge in current societies (e.g. Ravetz, 2001; Wynne, 1995; Beck, 1986; Jasanoff, 1990; Renn, 2006; Lofstedt, 2005; Nowotny et al., 2001; Harremoës et al., 2002; Wynne, 1982). The presence of uncertainty challenges, or at least complicates, risk management and assessment.

The economist Knight argues that it is possible and necessary to distinguish sharply uncertainty from risk (Knight, 1921). In this 'positivistic risk paradigm' (Van Asselt, 2000; Krayer von Kraus et al., 2005), or 'classical risk paradigm' (WRR, 2008, Gezondheidsraad,

2008) risks are presented as the calculable, hence controllable, islands in the sea of uncertainty (compare Nowotny et al., 2001). Positivists interpret risk as referring 'objectively to the circumstances of the physical world' (Thompson and Dean, n.d; Shrader-Frechette, 1992). Positivists distinguish between risk management and assessment, and consider expert calculation the preferred means to settle risk issues (compare Van Asselt, 2000; Krayer von Kraus et al, 2005). On the contrary, constructivism can be interpreted as a way of reasoning that views risk as a social construct. According to Klinke and Renn, constructivists view risk and risk assessments as 'constituting mental constructions which can be checked at best against standards of consistency, cohesion and internal conventions of logical deduction" (Klinke and Renn, 2002). According to constructivists, it is only relevant to talk about risk in particular settings (compare Hilgartner, 1992; Adams, 1995). Furthermore, constructivists view risk management and assessment to be inseparable activities, in which value differences are at the core.

This dichotomy, in line with the positivistic view, remains the dominant way of looking at risk (compare WRR, 2008). However, an increasing number of authors (see, for example, Vercelli, 1995; Gezondheidsraad 1995, 1996, 2008; Nowotny et al., 2001; Van Asselt and Vos, 2006; Van Asselt and Vos, 2008; Renn 2006; Renn and Walker, 2008; WRR, 2008) argue that uncertainty and risk cannot as easily be distinguished as is assumed in the positivistic risk paradigm. Some risks are simple, in the sense of certain enough to be calculated as a function of probability and effect. In those cases, due to past experience and the associated availability of statistical data, probability can be estimated and a measure of effect can be derived. Simple risks are calculable and relatively easy to manage. Existing risk assessment tools and risk management approaches suffice.

However, many risks are not that simple.[1] Risk refers to potential events with consequences that one or more actors evaluated as negative. In many cases such events and/or consequences are highly uncertain, because they consider new hazards or involve situations with structural changes compared to the past. In the latter case, the available statistics are of limited value to estimate probability and effect

[1] In its 2008 scientific report 'Uncertain Safety', the WRR calls for a paradigm shift with regard to the governance approach to risks. They argue that the classical risk paradigm (in the body text also referred to as 'positivistic paradigm'), and its policy based on 'simple' risks is outdated, but should not disappear. Rather, a paradigm shift to risk governance should take place, focusing policy on uncertain risks and ambiguous risks. Simple risks, which produce little to no uncertainty (WRR, 2008) i.e. 'certain uncertainty' (Van Asselt, 2000) should be seen as the special cases rather than the norm that they constitute in current policy-making in risk management and assessment practices.

as the historical data no longer do justice to current and future situations. Furthermore, many risks are complex, which also creates uncertainty. They involve a multitude of effects, of which some may extend into the long term, that cannot be easily assessed and compared nor can measures of effect, if available, easily be added. Risks may also involve complex causalities, non-linear relationships as well as interactions between effects. Uncertainties about the relevant phenomena and the underlying multi-causal relationships, i.e. several factors and interaction between those factors that contribute to effects, may render it difficult, if not impossible, to determine what may happen. Several cases discussed by scholars (Harremoës, 2002; Bridges and Bridges, 2001; Ibareta and Swan, 2001; Mourik, 2004; Murphy, 2006) consider the problem of latent connections and the lack of established mono-causal relationships. Such risks are thus not, or at best only partly, calculable, because the probability of occurrence or the damage cannot be estimated, and even the potential hazard and the relevant causalities may not be established, although there may be suspicions of danger. In the absence of a causal explanation or evidence-based refutation, the idea of exposure can still invoke societal controversy.

Adding to the debate on uncertain risks, Van Asselt and Vos (2006) defined 'uncertain risks' as risks that may be distinguished from 'safe uncertainties', because they pertain to uncertain situations that may result in one or more effects that are valued negatively or considered unacceptable by at least one, but possibly more, societal actors. Examples of situations that may involve such risky uncertainties as the introduction of a new (chemical or genetically modified) substance, the extensive application of a new technology or unprecedented human intervention in the environment. Uncertainties about the underlying processes and the complex multi-causal relationships between causes and effects may render it difficult, if not impossible, to determine what may happen.[2] The most important reason to recognize different types of risk and especially to differentiate between 'simple risks' on the one hand and 'uncertain risks' on the other is that different types of risk require fundamentally different assessment, management and communication approaches (e.g. Wynne, 2001; Lofstedt, 2005; Renn, 2006; WRR, 2008).

Uncertainty is not simply the absence of knowledge (compare Van Asselt, 2000 with Levidow, Carr, and Wield, 2005). Experts and scientists quite often have informed ideas on which uncertainties may be important and why, what are underlying sources of uncertainty,

[2] For a more detailed classification of risks, compare Van Asselt (2000) and Renn (2006).

whether and how uncertainties may be reduced or at least better understood, which interpretations of uncertainty seem valid and which contradict the established state-of-the-art. The whole of answers to these questions can be referred to as 'uncertainty information'. Experts can provide such uncertainty information, but they cannot provide certainty about uncertain risks. Although it is argued that addressing uncertainty in risk analysis is vital, it is also often noted that treatment of uncertainty is not a straightforward job, but a challenging activity. Numerous scholars agree that there cannot be a single approach in addressing uncertainty that will be adequate in all circumstances and contexts (*inter alia* Bailey et al. (1996); Friedman et al. (1999); Harremoës (2003); Heal and Kristroem (2002); Jaeger (1998); Klinke and Renn (2002); Morgan (2003); Morgan and Henrion (1990); O'Riordan and McMichael (2002); Pahl-Wostl et al. (1998); Pollack (2003); Ravetz (1997); Stocking (1998); Van Asselt and Petersen (2003); Van Asselt and Rotmans (1996, 2002); Van der Sluijs (1997); Walker and Marchau (2003) and Walker et al. (2003).

13.3. Regulation in Situations of Uncertain Risks

In our previous work, we have analysed various cases of risk regulation at the European level. The first case, the so-called Pfizer case, deals with the use of a certain antibiotic (virginiamycin) in feed as a growth promoter. We furthermore analysed three cases of EU regulation on GMOs. The complexities with which regulatory authorities and courts were faced in situations of uncertainty, as well as the uncertainty paradox, were clearly demonstrated within these cases. Below, we summarise the various cases.

13.3.1. The Pfizer Case: EU Regulation of Feed Additives and the Use of Antibiotics in Feedstuffs

The incorporation of additives in feedstuffs has been regulated at the Community level since 1970. In 1996 a Community authorisation system was introduced according to which only additives that had obtained prior Community authorisation could be used in feedstuffs. This regulatory regime includes the possibility for a Member State to temporarily suspend or restrict the use of an authorised additive after having shared the grounds on which it considers the additive dangerous with the other Member States and the Commission. In these cases, the Commission has to confirm the national decision or to decide that the Member State must lift the measure.

In accordance with this so-called safeguard procedure (Article 11, Council of Ministers, 1970), Denmark notified the Commission in

January 1998 that it had banned the use of the antibiotic virginiamycin as a growth promoter because of the risk that resistance to that antibiotic would be transferred from animals to humans. The Danish authorities relied on a report of their National Veterinary Laboratory. The Commission subsequently submitted this Danish scientific report to a European Committee – the Scientific Committee on Animal Nutrition (SCAN) – for advice. The SCAN concluded that the use of virginiamycin did not constitute an immediate risk to public health in Denmark.

The Commission, however, with reference to the precautionary principle, was not convinced and proposed to ban the use of this antibiotic. It submitted its draft decision to the Standing Committee on Feeding-stuffs (StCFe) for approval. This Committee was however unable to reach an opinion. The relevant provisions require that, in such a situation, the Commission sends its draft decision to the Council, which then makes a decision according to the so-called regulatory committee procedure. The Council confirmed the Commission's position and subsequently adopted a regulation banning the use of virginiamycin together with three other antibiotics as additives in animal feeding-stuffs. Pfizer, producer of virginiamycin, challenged this decision before the Court of First Instance (CFI).

Our analysis revealed that from the outset of the regulatory process, i.e. the point at which the Commission approached SCAN for advice, the role of the experts had already been framed in terms of providing certainty about uncertain risks. The Commission asked SCAN to give an opinion on whether the conclusions in the Danish report 'are scientifically justified' and on the question of 'whether or not' the use of the virginiamycin as a growth promoter constituted a public health risk at present or could constitute such a risk in the future. These terms of reference can be interpreted as a request for a 'plausibility proof', namely statements by experts in which their risk judgements are cast as conclusive evidence on the existence or non-existence of an uncertain risk (Van Asselt and Vos, 2008). Such a request has the tendency to be seen as demanding conclusive evidence on whether something is a risk. Such requested certainty about uncertain risks seems highly incompatible with uncertainty as the core of the precautionary principle, which implies that neither definite proof nor evidence is available. The Commission asked SCAN for a decisive answer as to whether the risk is a hazard, instead of asking for uncertainty information. The Commission placed everyone concerned in the uncertainty paradox. The whole regulatory endeavour further sustained the uncertainty paradox, with the consequence that, in the end, the Court was forced to evaluate the merits and validity of scientific claims.

In our analysis of the whole regulatory chain, from the Commission's request for a scientific opinion to the Court's ruling, we observed that scientific experts, regulatory authorities (the Commission and the Council) and judges tried to worm themselves out of the uncertainty paradox in order to prevent stagnation of the regulatory process. The SCAN experts tried to provide a satisfactory plausibility proof, but uncertainty information crept into its considerations. Throughout its opinion, SCAN provided uncertainty information, as in this case 'science could not answer the straightforward question of whether there was a risk of transfer of resistance, now or in the future' (Forrester and Hanekamp, 2005). Instead of following the requested plausibility proof, the European institutions reinterpreted pieces of uncertainty information in order to construct uncertainty, which was subsequently used as argument to apply the precautionary principle. Thus, the Council and Commission interpreted the uncertainty information provided by SCAN completely differently than experts. In doing so, the institutions implicitly admitted that reasoning about the 'plausibility' of uncertain risk involves normative and subjective judgments, on which basis they implicitly considered it legitimate to 're-do' the work originally delegated to the experts.

Although the uncertainty paradox put SCAN, the Council and the Commission in an uncomfortable straightjacket, it is clear that the Court in particular was confronted with a no-win situation. A closer look at the Court's judgment reveals that the Court relentlessly repeats that it is only in the position to carry out a limited review (see for example, paragraph 393 of the judgment, European Court of First Instance, 2002). However, the Court was unable to stick to a limited review and struggled with its role in the scientific debate:

> 'the Court nevertheless finds that the parties' arguments, supported in each case by the opinions of eminent scientists, show that there was great uncertainty, at the time of adoption of the contested regulation, about the link between the use of virginiamycin (...) and the development of (...) resistance in humans' (Paragraph 393).
> 'the various experiments and observations (...) were not mere conjecture but amounted to sufficiently reliable and cogent scientific evidence for [the Community institutions] to conclude that there was a proper scientific basis for a possible link between the use of virginiamycin (...) and the development of (...) resistance in humans' (Paragraph 389).

Interestingly enough, the Court concluded that:

> 'the Community institutions had a scientific basis on which to reach a decision, since they could draw on some results of the most recent scientific research on the matter' (Paragraph 369).

This is a clear manifestation of the uncertainty paradox: while on the one hand great uncertainty is emphasized, at the same time, it is suggested that sufficiently reliable and cogent scientific evidence and a proper scientific basis are available.

Our analysis of the Pfizer case reveals that the Court was faced with a deadlock that emerged from how the uncertainty paradox was visualized by the Commission and later also by the Council. The Court attempted to overcome this deadlock by constructing uncertainty, which it then used to argue in favor of the application of the precautionary principle, whereby it upheld the Council's ban. Like the Council, the Court used uncertainty to legitimize its ruling (paragraph 142). The irony of the case is that Pfizer facilitated the Court's construction of scientific uncertainty by creating an image of an uncertain scientific knowledge base in order to argue that a risk had not been proven. All the science involved, whether brought in by SCAN or Pfizer, was therefore merely used to demonstrate uncertainty, which in its turn was used as a sufficient basis for the application of the precautionary principle.

Ultimately, the Court hid behind uncertainty, a non-legal concept. Apparently the Court interpreted uncertainty as arising from contrasting scientific opinions. Where the Commission used the scientific knowledge contents of SCAN, the Court used these scientific arguments merely to conclude that there are contrasting scientific opinions, which it took as sufficient evidence of uncertainty. The Court 'saved' itself by viewing uncertainty as something it can observe itself, i.e. as being constituted by contrasting opinions between experts it considers as being qualified. As the Court cannot balance the scientific arguments, it is arguably inclined to assume equal standing of opinions and counter-opinions. Thus, in the end, the Court managed to produce a ruling, but the price for the escape from the impasse may be (too) high.

13.3.2. EU Regulation of GMOs

In our analysis of EU decision-making on genetically modified organisms (GMOs) we studied three cases pertaining to the import of genetically modified organisms (GMOs): NK603, a genetically modified maize made resistant to a particular herbicide to increase farmers' control of weed; GT73, a genetically modified maize made resistant to the same herbicide as NK603; and MON 863 X MON 810, a maize composed of two genetically modified maize variants containing insecticidal proteins.

Inspired by Ravetz (2001), we use the following notions to refer to specific main actors in these cases:

- Risk producers – those pursuing potentially hazardous activities or technologies: Monsanto.
- Risk assessors – experts seeking to analyze risks: the GMO panel of the European Food Safety Authority (EFSA).
- Risk managers – decision-makers charged with regulating risks: the European Council and Commission, and the Member States.
- Risk protesters – those objecting to new technologies or activities with reference to potential risks: Greenpeace and Friends of the Earth. These risk protestors do not have a formal role in this regulatory regime, but they aim to influence the regulation process through lobbying, protesting and critical reports.

We concluded that in these three cases as well, the uncertainty paradox was crucial. The risk regulation process began with an application by the risk producer Monsanto to an EU Member State to market a genetically modified product in that country. As the risk producer, Monsanto is legally required to carry out an assessment. Their assessment had been submitted to the relevant competent authority of the Member State. When the national assessment was completed, it was forwarded to the European Commission. The Commission then asked the GMO Panel of the European Food Safety Authority (EFSA), established in 2002 as an independent body for science-based risk assessment, to consider the risks of the genetically modified product in question. The GMO Panel had to operate within strict time limits and it lacks the resources and facilities to test products. Our analysis demonstrated that this meant that EFSA's risk assessments were *de facto* meta-reviews of Monsanto's assessments in place of an independent examination. Thus the claimed independence of EFSA was compromised by reliance on Monsanto's research facilities, tests, knowledge and its willingness to disclose information.

The Panel's advice was forwarded to the relevant standing committees comprised of representatives from each Member State. This panel failed to reach an opinion. This meant that the Commission had to refer the draft decision to the Council of Ministers of the EU. Similarly divided on these issues, the Council too failed to reach a majority stance and could not adopt a decision. As in the Pfizer case, this meant that the final decision was up to the Commission, which functions in such situations as 'deal maker'. This regulatory procedure (Council decision 1999/468, Article 5) was intended to serve as a means for breaking occasional deadlocks. Yet, in the Pfizer case as well as the three GMO cases that we analysed, this turned out to be the *de facto* standard operating procedure.

Case	Role		
1. Pfizer Case	Risk Producer	Risk Assessor	Risk Manager
Pfizer			
SCAN			
EU Commission			

European Court			
2. EU GMO Cases			
Monsanto			
EFSA GMO Panel			
EU Commission			

Our analysis indicated that in the case of EU regulation of NK 603, GT 73 and MON 8106 MON 863, the uncertainty paradox was sustained and reinforced by the interplay of four mechanisms.

1. The first pattern is uncertainty intolerance on the part of Monsanto and EFSA. Our analysis suggested that Monsanto's safety assessments constituted deliberate efforts to transform any uncertainty about risk into absolute certainty about safety. To this end, they avoid uncertainty in their communication, define it away in their reports and attempt to suppress tests that may question the impression of absolute certainty that they wish to create. The combination of these assessment behaviours – claiming irrelevance, creating a smoke screen and suppression of tests – provide further evidence for our evaluation of Monsanto's stance: uncertainty intolerance is visible in their framing and assessment behaviour.

2. We also observed uncertainty intolerance on the part of EFSA's GMO panel, which is in line with the earlier observations of Levidow, Carr and Wield (2005). They concluded that the opinions of EFSA's GMO Panel 'generally indicate no uncertainty' that might trigger extra risk management measures and they 'have framed scientific uncertainties in such a way that they can be resolved by extra information, or can be readily manageable, or can be deemed irrelevant to any risk'. The risk assessor partly inherited Monsanto's uncertainty intolerance, as EFSA's risk assessments were in fact meta-reviews of Monsanto's assessment, but our analysis suggests that the intolerance cannot be fully explained by inheritance. EFSA's own uncertainty intolerance was visible in its boundary work. Boundary work, a notion coined by Gieryn (1983, 1999), is a strategic and purposeful act in which boundaries are drawn between realms, for example, between science and non-science and between science and politics. Boundary work enabled EFSA to claim irrelevance and to construct authority claims which served as building blocks in creating plausibility proofs. Our analysis demonstrates that in instances that could have been read as uncertainty (Member States' concerns, adverse effects, open questions), the GMO panel actively evaded uncertainty through boundary work, in place of discussing these uncertainties and exploring whether and how they may be important.

3. A further mechanism is the tendency to equate uncertainty with risk, which (further) confined risk producers and risk assessors to the role of uncertainty-intolerant producers of plausibility proofs. We observed that both the risk producer (Monsanto) and the risk protestors (Greenpeace and Friends of the Earth) tended to equate uncertainty with risk, notwithstanding the fact that they have opposite positions in the GMO debate: the risk producer tried to avoid uncertainty in order to demonstrate safety, while the risk protestors highlighted uncertainty to demonstrate risk. This tendency to equate uncertainty with risk sustains the uncertainty paradox as it hampers the production and sharing of uncertainty information.

4. Finally, technocratic provisions resulted in an even stronger, if not central, *de facto* political role for EFSA, with the consequence that the role of EFSA's uncertainty intolerance further increased. EFSA fails to use the windows of uncertainty. The effective message of EFSA's assessment is a plausibility proof, although such a non-risk opinion was arguably not requested by the Commission. This

production of plausibility proofs can be read as an uncertainty intolerant interpretation of the goal of the assessment. We observed that the technocratic provisions allow EFSA's uncertainty intolerance to dominate the regulatory process. EFSA fails to provide any uncertainty information and all uncertainty issues that have been brought forward by other actors, i.e. Member States or risk protesters, were pushed aside.

On the basis of our analysis, we concluded that political responsibility for a highly sensitive risk dossier was lost (which we term a 'political deficit')[3], notwithstanding all institutions and procedures being in place and the pretence of certainty and control being created.

13.3.3. Pfizer and GMO Cases Compared: Risk Aversion versus Risk Intolerance

Both the Pfizer as well as the three GMO cases demonstrate that the way that the uncertainty paradox is constructed or evolves depends on the role of science and expertise (compare Wynne, 2001; Levidow, Carr, and Wield, 2005; Jasanoff, 2005; and WRR, 2008, all of whom emphasize the need to rethink the role of science and expertise in risk regulation). Of particular interest is the way in which risk assessors obtain a role in regulation and the way in which these roles are institutionalised. In the final part of this paper, we would like to compare the various cases in terms of the role of uncertainty intolerance, and to a lesser extent the role of technocratic provisions, in order to better understand the mechanisms that play a pivotal role in creating and/or sustaining the uncertainty paradox.

The analysis of the cases has demonstrated the manifestation of the uncertainty paradox. However, a closer look reveals that the paradox in the Pfizer case is the result of a different process than that in the GMO cases. Some distinctions become apparent that are related to uncertainty intolerance.[4] It could be argued that in general the

[3] The term political deficit is partly based on the debate on the 'democratic deficit' and whether it exists within the EU regulatory framework (Majone, 2000, 2005; Folesdale and Hix, 2005; Moravcsik, 2004). The term was first coined by UK MEP Bill Newton Dunn in a pamphlet in the 1980s and refers to the argument that the 'European Union and its various bodies suffer from a lack of democracy and seem inaccessible to the ordinary citizen because their method of operating is so complex' (European Commission, 2009). According to proponents there exists a 'gap between the powers held by European institutions and the ability of European citizens to influence the work and decisions of those institutions' (McCormick, 1999). We argue that the political deficit is of a more fundamental nature, since it ends up being an 'administrative', or, more accurately, a very technocratic, decision on a highly political dossier.

[4] In psychology, the term uncertainty intolerance is used to refer to individuals who 'find it unacceptable that something negative may happen, regardless of the chances. As a relief mechanism, [these] people look for certainty' (Vlaeyen, 2008).

perception of uncertainty intolerance is conflated with what in the risk perception literature is usually referred to as 'risk aversive' (Slovic et. al, 2006), namely considering it unacceptable that something negative might happen, regardless of the chances (Douglas, 1985; Adams, 1995). Unless safety is certain, risks are perceived to be dangerous (compare Adams, 1995; Van Asselt, 2000). In the risk literature it is also recognised that: 'The less conclusive the science, the more influential become the filters through which risks ... are perceived.' (Adams, 2007: 2)

However, risk aversion is only one of the possible perceptive filters towards risk. In this context, uncertainty intolerance refers to the attitude and behaviour of institutions, organisations or groups and in particular to situations in which uncertainties are not acknowledged, deemed irrelevant, or are simply evaded, instead of genuinely and systematically investigated. Uncertainty intolerance is associated with an unwillingness to demand and produce uncertainty information and it indicates whether or not individuals, groups and organisations show an openness towards the possible inconclusiveness of science.

In our analysis, we prefer to distinguish between uncertainty intolerance (namely searching for certainty) and risk aversion, as, in view of the current state of the art, we would like to be able to consider the possibility that uncertainty intolerance does not necessarily imply risk aversion and vice versa. We discussed the Pfizer case in order to demonstrate how and where uncertainty intolerance can be observed in the process. As we showed, the Commission as risk manager posed an unequivocal question to SCAN, the risk assessor, about the existence of a risk. This question can be read as uncertainty intolerant. We observed in our previous analysis that SCAN's response seems to demonstrate more uncertainty tolerance in their relatively uncertainty tolerant scientific assessment:

> 'the use of virginiamycin as a growth promoter does not constitute an immediate risk to public health in Denmark. The nature of resistance to the streptogramins is *not fully understood and mechanisms other than those described above may operate*' (Section 3, Scientific Committee on Animal Nutrition, 1998; emphasis added).

Although the Commission's request qualified as uncertainty intolerant, interestingly enough the Commission (implicitly) recognised the uncertainty information and reinterpreted it in a risk aversive manner. We observe that in line with our discussion above, the Commission and the Council pursued a rather constructivist use of science by reinterpreting SCAN's assessment.

On the one hand, we observed that risk managers (the Commission and the Council) turn to scientists for certainty ('is there a risk?'), by

which they fail to recognise science as inconclusive due to uncertainty. Furthermore, by neglecting to look for uncertainty information, their behaviour can be identified as uncertainty intolerant, and this in turn could be read as a positivistic point of view. However, their subsequent actions, i.e. the reinterpretation of the unsystematically provided uncertainty information in experts advice, are more in line with a constructivist acknowledgement of science with its emphasis on interpretation. Thus, the risk manager's behaviour seems to be uncertainty tolerant, but it is fair to say that its level of uncertainty tolerance remains rather marginal.

In order to invoke the precautionary principle (see Box 1) one of the requirements stipulated in the legal formulations (Maastricht Treaty, Article 174 EC) is that a risk assessment needs to be carried out. After an uncertainty intolerant point of departure on the side of the Commission (risk manager) demanding a plausibility proof from SCAN, the Commission showed even more uncertainty intolerant behaviour in a second instance by its reinterpretation of a relatively uncertainty tolerant scientific assessment: the Commission attempted to extract an unequivocal answer to the question whether the feed additives involve a risk. So we conclude that the attitude of the Commission as derived from its behaviour should be characterized as uncertainty intolerant, notwithstanding its constructivist use of expert knowledge.

However, in the next stage, the Commission attempted to invoke the precautionary principle. This principle stipulates that it can be applied in cases of uncertainty. Hence, the Commission needs to acknowledge uncertainty at this particular point. So it switched from an uncertainty intolerant stance to an uncertainty oriented approach. In this process of highlighting uncertainty with the purpose of invoking the precautionary principle, the risk manager is confronted with the requirement of a risk assessment. Subsequently, the Commission presents SCAN's advice as the required risk assessment. Interestingly enough however, SCAN explicitly stated that:

> 'However it is of the opinion that a full risk assessment cannot be made until quantitative evidence of the extent of transfer of antimicrobial resistance from livestock sources is obtained and the significance of this within the overall use of antimicrobials for clinical and non-clinical purposes evaluated.'

Hence, the report which stipulates that a risk assessment cannot be carried out due to the presence of too much uncertainty is being presented as the required risk assessment. In sum, the uncertainty intolerant framing of the risk manager resulted in relatively uncertainty tolerant advice with a constructed plausibility proof on request. The

plausibility proof was set aside, and the uncertainty intolerant regulator even highlighted uncertainty in order to be able to invoke the precautionary principle. To that end, the risk manager had to present the advice – which it had previously set aside – that literally claimed that a risk assessment is impossible because they argued that there was too much uncertainty to be able to carry out a risk assessment. This course of behaviour demonstrates the kind of unintelligible decision-making which may arise in situations in which the uncertainty paradox is present.

The uncertainty intolerant behaviour of the Commission (and the Council in the Pfizer case) is crucial in reproducing the uncertainty paradox, which in turn results in a pointless process. In this particular case, the uncertainty intolerance on the side of the risk manager weighed heavy on the process, pushing aside the relative uncertainty tolerant behaviour of the risk assessors.

Concurrently, at first sight, the Commission, the Council and at a later stage, the Court, seem to be uncertainty tolerant because they take 'uncertainty' as a point of departure to invoke the precautionary principle. At the same time, the Commission, Council and Court deal with experts in an uncertainty intolerant way, since they demand certainty on whether there is a risk or not. However, the institutions use the fact that the experts are unable to provide this demand for certainty to label the problem as 'uncertain'. Subsequently, this labelling forms the basis for conducting a certain policy strategy, namely invoking the precautionary principle in a risk-aversive manner. Such uncertainty labelling should not be equated with uncertainty tolerance. The case can instead be understood in terms of a mechanism which is described in the policy science literature as the 'problem-solution-couple' (e.g. Diekman, n.d). By referring to the problem as being uncertain, a certain problem-solution-couple is activated, namely the uncertainty-precautionary principle couple.

By attempting to infer the precautionary principle and by dismissing the uncertainty information, the behaviour of the Commission, Council and the Court can be perceived to be not only uncertainty intolerant (the failure to systematically investigate uncertainty at first), but also risk averse, by trying to invoke the precautionary principle on the grounds that experts cannot provide certainty.

In the GMO cases, uncertainty intolerance is also visible. However, the actors and the setting of this process differ from the Pfizer case. In this case, the Commission (also in the role of the risk manager) does not frame its question to the experts in an uncertainty intolerant manner: it does not ask whether the GMOs are a risk, but in all three cases, it asked EFSA's GMO panel to 'consider whether there is any

scientific reason to believe' (EFSA 2003; 2004 (a), (b)) that the placing on the market of the GMOs might cause adverse effects to human health or the environment. The particular formulation 'whether there is any scientific reason to believe' is relevant when we compare it with the closed question (i.e., whether or not the activity constitutes a risk) that the Commission asked in the Pfizer case. It can be argued that the terms of reference to EFSA were more uncertainty tolerant in the light of the following two elements: firstly, instead of asking for a decisive answer on and proof as to whether the risk is a hazard, the Commission asked for indications that hint at adverse effects; and, secondly, instead of referring to science as the source of absolute truth and certainty, with the phrasing 'to believe', the Commission seemed to accept that science cannot provide certainty about uncertain risks. The terms of reference could therefore have been read as an invitation to systematically discuss the uncertainties involved and to provide uncertainty information.

Thus, what is particularly interesting here, and contrary to the Pfizer case, is that the process seems to have started from a more uncertainty tolerant framing. However, EFSA failed to use the window of uncertainty and answered as if the Commission had asked a closed question, thereby demonstrating clearly its uncertainty intolerance. However, in this case EFSA does not present itself as risk averse, since they do not consider the risk to be unacceptable, regardless of the probabilities.

When taking a detailed look at the mechanism of uncertainty intolerance in the Pfizer case and the EU regulation of GMOs, the risk managers' and assessors' attitudes and behaviours towards uncertainty are reversed. This indicates that uncertainty intolerance is not so much an attitude or behaviour that can be ascribed to a particular actor within the risk regulatory process. Risk managers are not by definition uncertainty intolerant nor are risk assessors by definition uncertainty tolerant, and vice versa. Our case study material does not enable us to explain uncertainty intolerance, we can only observe that it is not affiliated with a particular role in the risk regulation process (i.e. otherwise the same type of actor would be in the same quadrant in Figure 1). Furthermore, the comparison of the various cases suggests that uncertainty intolerance is also relatively independent of the characteristics of the issue at hand. Otherwise, uncertainty intolerance would have had to be visible for both the risk assessors and managers in one case (i.e. the actors in the same case would be in the same vertical part of the figure).

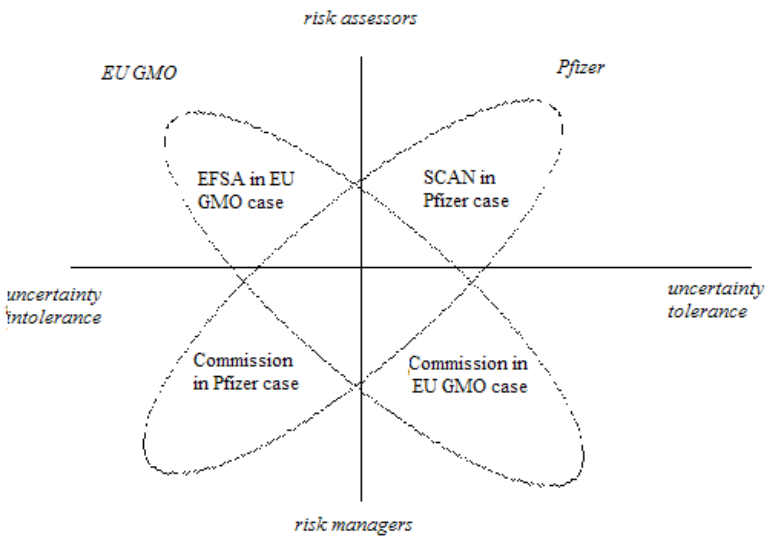

Figure 1. Dealing with uncertainty in two regulatory cases: a mirroring image

If the perspective of risk assessors and managers are congruous in a certain case, it could be presumed that uncertainty intolerance, at least partly, would be nourished by the characteristics of the issue at hand.

In both cases, the actor who turned out to be central in the actual risk regulation process (the risk manager in the Pfizer case and the risk assessor in the GMO cases) could be qualified as uncertainty intolerant. Throughout the various processes, actors or moments can be identified that expressed relative uncertainty tolerance; however, the dominance of the uncertainty intolerant (central) actors pushed uncertainty intolerance to centre stage. This seems to suggest that the attitude towards uncertainty of a critical actor is an important explanation for the manifestation of the uncertainty paradox and associated regulatory problems.

This analysis provides a more subtle insight into the uncertainty paradox. In our earlier work, we define the uncertainty paradox as situations in which, although uncertainty is acknowledged, requests for certainty are still made by policy makers and risk managers to experts. However, in these particular cases it seems that although uncertainty is acknowledged and some actors express uncertainty tolerance, crucial actors demand certainty at the same time. Even when (some)

uncertainty information is provided (implicitly or explicitly) by Member States, risk protesters, the risk managers (GMO) and/or the risk assessors (Pfizer), a dominant uncertainty intolerant actor may be able to push this aside and to impose uncertainty intolerance. Influential uncertainty intolerant actors within risk regulation, whose dominance might be facilitated by technocratic provisions for extraordinary circumstances that developed into the *de facto* standard operating procedure, are likely to invoke the uncertainty paradox or sustain it. To turn it the other way around, the presence of uncertainty tolerant actors in the process does not mean that the uncertainty paradox will not appear, which in turn may result in unintelligible risk regulation.

We argued that we considered it more appropriate to distinguish between uncertainty intolerance and risk aversion, as we did not want to assume that they necessarily constitute each other. The empirically informed analysis of actual risk regulation suggests that this distinction is indeed needed. In order to better understand and denote these particular decision-making processes it is useful to distinguish between uncertainty intolerance and risk aversion. In particular, this is demonstrated by the finding that in the Pfizer case we can observe a dominant actor who is uncertainty intolerant and risk averse, whereas in the GMO cases, the critical actor is uncertainty intolerant, but not risk averse.

13.4. Conclusion

Innovation creates uncertainty and thus regulation of technology imply decision-making in uncertainty and about uncertain risks in particular. Our research shows that the uncertainty paradox is an observed pattern in such a decision-making structure. How is this paradox brought about and sustained? Empirical research suggests a number of mechanisms, of which uncertainty intolerance and technocratic provisions play a particular role, as investigated in this paper. To that end, we have defined uncertainty intolerance as the attitude and behaviour of institutions, organisations or groups applied to situations in which uncertainties are not acknowledged, deemed irrelevant, or are simply evaded, instead of genuinely and systematically investigated.

We have argued that uncertainty intolerance should not be equated with risk aversion, but suggested that in entertaining the notion of uncertainty intolerance in the context of risk research, it is more appropriate to distinguish between uncertainty intolerance and risk aversion. Our research furthermore suggests that uncertainty intolerance on behalf of a dominant actor is crucial in bringing about and sustaining the uncertainty paradox. The dominance of a particular

(uncertainty intolerant) actor may be caused and/or reinforced by particular technocratic provisions. This revelation makes clear the need for further research on the relationship between risk aversion and uncertainty intolerance, whereby resort to psychology studies may be of help for a further elaboration and clarification of this relationship. The above also makes plain that the continuation of empirical research by means of case studies of regulatory decision-making is of great importance in the attempt to better understand and to formulate suggestions for overcoming the uncertainty paradox.

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Chapter 14. De Facto Governance of Nanotechnologies

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Abstract
New and emerging technologies, especially nanotechnologies with the structural uncertainties about their eventual functionalities and risks, are a challenge to governance. What is striking is how much actual governance is already occurring in and around nanotechnology without any particular actor being responsible for the emerging governance arrangements. Mapping what is happening in terms of societal agenda-building about risks of nanotechnology, including voluntary codes of conduct and calls for responsible development, allows me to flesh out the notion of *de facto* governance by showing how it works in the domain of nanotechnologies. This then leads me to speculate about a further governance arrangement: the internalization of requirements of "responsible development" of nanosciences and nanotechnologies in actual technological and product-development choices and strategies.

14.1. Introduction

New and emerging technologies, especially nanotechnologies, with the structural uncertainties about their eventual functionalities and risks, are a challenge to governance. Regulatory agencies in Europe and the US review existing regulation and consider voluntary reporting as a transitional measure. Risk governance is opened up to include public dialogues and deliberative processes. What is striking is how much actual governance is already occurring in and around nanotechnology, without any particular actor being responsible for the emerging governance arrangements.

Thus, the first aim of this paper is to map what is happening: the actions and interactions and how these add up to outcomes at the collective level that function as governance arrangements. In that way, the paper is explorative: it is an attempt to understand what is occurring and is partly based on the author "moving about" as a self-styled anthropologist in the world of nanotechnologies. What is clear is that the emerging governance arrangements have a distributed character. This is captured by using the notion of governance, which, in contrast to government, is distributed almost by definition. The additional point, however, is that bottom-up actions, strategies and interactions are constitutive for these arrangements rather than that they are the result of an opening up of an earlier centralized arrangement to make it more distributed – a common way to introduce

the notion of governance (Van Kersbergen and Van Waarden, 2004). To emphasize the strong bottom-up character of what is happening, I introduce the notion of *de facto* governance.

This leads to the second aim of this paper: to flesh out the notion of *de facto* governance by showing how it works in the domain of nanotechnologies. The recognition of the importance of *de facto* governance implies that attempts at regulation can be located as interventions in emerging *de facto* governance, and will depend on it for their effectiveness.[1] This is similar to the way in which Henry Mintzberg (1994) viewed intentional (and often top-down) strategy in firms and other organisations, noting that the latter's effects will depend on the interaction with *de facto*, or in his words 'pattern' and 'emergent', strategies, that are out there already. While society should not be seen as an organisation writ large, the dual dynamics outlined by Mintzberg occur all the time. And they can add-up to what one could call a societal agenda.

This chapter has a third aim, linked to what I see as an intriguing potential *de facto* governance pattern: the internalization of requirements of "responsible development" of nanosciences and nanotechnologies in the actual technological and product-development choices and strategies. Something of the sort is happening, as I will show, and the question then is what this implies for the governance of nanotechnologies. The further question is whether internalization of such considerations might occur for other emerging technologies as well. If this occurs, or is expected to occur, it will create a new regime for shaping technology development within society.

After fleshing out the notion of *de facto* governance, I will present and discuss two recent developments. Firstly, how a socio-technical agenda about promises and concerns over nanotechnology emerged, in which risks, and in particular risks of nano-particles, became dominant. And secondly, how "responsible development" has become an integral part of the discourse and, to some extent, of the practice, of nanotechnology. This then allows me to inquire into the possible internalization of societal considerations in ongoing development of nanosciences and nanotechnologies. In the concluding comments, I will come back to governance issues.

[1] This point has been made in implementation studies, starting with Presmann and Wildavsky (1984) and becoming almost a movement (of the "bottom-uppers") in the 1980s (see Hanf and Toonen, 1985). There is a tendency, however, to push to this background in actual policy making and implementation, because policy makers must show that it is they who are making a difference.

14.2. The Notion of De Facto Governance

In the broadest sense of the concept of governance, all structuring of action and interaction that has some authority and/or legitimacy counts as governance. Authors such as Van Kersbergen and Van Waarden (2004) and Kooiman (2003) recognize this, even if they do not thematise it. Governance arrangements may be designed to serve a purpose, but can also emerge and become forceful when institutionalized. The same move is visible in Voß et al. (2006: 8) where they argue that governance refers to "the characteristic processes by which society defines and handles its problems. In this general sense, governance is about the self-steering of society." They then develop this further:

> governance is understood as the result of interaction of many actors who have their own particular problems, define goals and follow strategies to achieve them. Governance therefore also involves conflicting interests and struggle for dominance. From these interactions, however, certain patterns emerge, including national policy styles, regulatory arrangements, forms of organisational management and the structures of sectoral networks. These patterns display the specific ways in which social entities are governed. They comprise processes by which collective processes are defined and analysed, processes by which goals and assessments of solutions are formulated and processes in which action strategies are coordinated. (...) As such, governance takes place in coupled and overlapping arenas of interaction: in research and science, public discourse, companies, policy making and other venues.

This view has been offered before, notably by Elinor Ostrom. As Scharpf (1997: 204) phrases it: "much effective policy is produced not in the standard constitutional mode of hierarchical state power, legitimated by majoritarian accountability, but rather in associations and through collective negotiations with or among organisations that are formally part of the self-organisation of civil society rather than of the policy-making system of the state (Ostrom, 1990)." A specific aspect is highlighted by Braithwaite and Drahos (2000: 10), where they note: "The global perspective on regulation we promote not only reframes individuals as subjects and objects of regulation (as in the drug case) and states as subject and object of regulation (by Moody's, the IMF, the Rothschilds and Greenpeace). Understanding modernity, we find, demands the study of plural webs of many kinds of actors which regulate while being regulated themselves."[2]

[2] Cited in Voß (2007: 34).

In such an encompassing view of governance, explicit attempts at steering intentional government arrangements will be seen as part and parcel of the overall process, not outside it. In economics, one can speak of endogenizing a factor (like new technology) that had been considered as external to economic analysis. Similarly, one can now say that government and design of governance arrangements must be endogenized to capture what is happening (Rip, 2006; cf. also Voβ, 2007).

Where governance of technology is discussed, it appears to be reduced to either innovation stimulation or regulation of actual and possible side-effects. The focus on performance of technologies (positive and/or negative) seems obvious, but it pushes to the background any broader consideration of governance. Science and Technology Studies (STS) have offered case studies and analysis showing that there is actually a lot of broader governance going on, but a lot of work is required to overcome the myopia of the prevalent view of technology being technically driven and/or naturalized. Moreover, as it is a prevalent view, the simple distinction between innovation stimulation and regulation is itself an example of a governance pattern in the broad sense.

This governance pattern derives from the gap between development and promotion of technology, and the responses of a society that emerged in the industrial revolution and stabilized in the 19th and early 20th century (Rip et al., 1995). A version of the gap is visible in the institutional separation between promotion and control of new science and technology, for example the difference in outlook and activities between government departments for trade and industry on the one hand and for social, health and environmental affairs on the other hand. To some extent this is a productive division of labour. But the separation of technology development (in firms, in public research institutes, in technical universities) from wider society implies that society has to respond, somehow, and is at a disadvantage because there have been investments in development already.[3] This 'gap' has led to an understanding of there being these two separate worlds, of "enactors" of new technology vs. (civil) society, as well as an understanding that with regard to new technology, civil society is "forced" into one or another of three reactions: to welcome it (this appears to occur for large parts of information and communication technology), to be fatalistic (for example about new infrastructural technologies), or to oppose it (as happened with agricultural

[3] At an early stage, however, it will be unclear what sort of performance and side-effects might be realized. This adds up to a dilemma of knowledge and control (Collingridge, 1980), which has become one motivation to do technology assessment at an early stage.

biotechnology). The recent interest of technology "enactors" in engaging civil society and having public dialogues on new technologies can be seen as an attempt to improve the possibility that society will respond in a welcoming rather than oppositional mode.

Another example of *de facto* governance arrangements, and one which has been highlighted by STS studies, are sociotechnical systems and infrastructures that together form the sociotechnical landscapes in which we live and move about. Roads and motorways serving automobile transportation, and the structures linked to them, are a clear example of how these "arrangements" shape what we do and cannot do, and with the authority that comes with their being invisible because self-evidently "given".[4] Systems and infrastructures can have political effects, for example the material unification of a country like the Netherlands (Schot et al., 2003); see also Anderson (1991) for the role of sociotechnical regimes and the idea of a national community. The socio-technical landscapes in/of our societies are like a constitution, even if not drawn up by a constitutional assembly. This includes the disciplining (of actors) necessary to maintain them and have them develop in certain ways. Systems like mobile telephony, including infrastructure as well as evolving customs and rules of use, are further examples of emerging socio-technical regimes which function as a *de facto* constitution.[5]

For emerging sciences and technologies it is not yet clear what their possible sociotechnical constitutional effects might be, but one can anticipate them based on an understanding of dynamics of technological change and its embedding in society (Rip and Te Kulve, 2008). This requires what one might call non-linear thinking, especially for technologies like nanotechnology that are enabling technologies. That is, nanotechnology delivers new materials and components to help create better devices and systems, and it is the latter which deliver the desired functionalities, and thus shows sociotechnical agency. Thus, nanotechnology is said to just improve performance, and sometimes allow new functionalities (e.g. dirt-repellent surfaces), and

[4] An example the "given" character of sociotechnical governance arrangements, often quoted in the STS literature, are the overpasses on Long Island, which continue to "govern" what is possible and what is not possible even after Robert Moses' original intentions became irrelevant (Winner, 1980). Their designer, New York city architect Robert Moses, created them to keep New York's black and poor whites (who had to use buses at the time, the 1920s and 1930s) away from the beaches and parks he had created on Long Island. He tried to create a material constitution for his preferred social order, and while it may have worked for a time, this particular constraint on behaviour has become irrelevant now that every American can use a motor car.

[5] This is an Actor-Network Theory notion, cf. how Latour (1991), for similar reasons, speaks of a "Parliament of Things". See also Verbeek (2006) on the morality of artifacts.

should therefore not be an object of concern *qua* its societal effects. Still, nanotechnology could lead to major changes where certain thresholds are passed. For example, when RFID (Radio Frequency Identification Devices) become cheaper and smaller thanks to nanotechnology, and thus more widely available as well as better implantable, all products can be traced individually and an "Internet of Things" becomes possible, as well as implants becoming easy and almost natural, leading to a view of the implantable and thus "readable" human. All this is still to come, but it is being discussed already and may lead to governance measures and arrangements. One could call this anticipatory governance (Barben et al., 2007). In fact, there is an anticipatory component to all governance (Rip, 2006).

The role of technology in governance is one of solidifying arrangements by embodying them in material form, or as Pels et al. (2002: 2) phrase it, "the performative and integrative capacity of 'things' to help make what we call society." In the case of the overpasses on Long Island (see note 4), certain governance modes were delegated to the things, which then did their governing job without being recognised as such. Since actual nano 'things' are still (mostly) in the future, such delegation is not possible. But there are expectations, and these can solidify into a forceful societal agenda that will govern strategic choices. One might call this "delegation to the future", and one can definitely see such "delegations" occurring in the domain of nanotechnology.

14.3. De Facto Risk Governance in the Domain of Nanotechnology

Before tracing the emergence of a risk governance agenda, it is important to note that 'nanotechnology' is an umbrella term, covering quite different scientific and technological developments that are similar only in that they work at the nano scale. In policy making, and to some extent in media coverage and public perception, it is the umbrella term that is used, so that differences are black-boxed even where they would be relevant.[6] In the risk debates, the reference is often just to nanotechnology, while the actual concerns, as well as present studies, are about nano-particles (and engineered free nano-particles at that). A reconstruction of the emergence of a forceful agenda will have to take this into account and maybe explain the focus on nano-particles.

For a reconstruction of the evolving risk governance debate and the resulting *de facto* agenda, I build on a study by Van Amerom and Rip,

[6] There is a *de facto* governance element involved in such processes: some terms become forceful exactly because they remain blackboxed.

based on a comprehensive study of documents (up till 2006) and on interviews and participant observation in relevant meetings, and partly reported in Rip and Van Amerom (2009). This study focused on societal and *de facto* agenda-building as the key phenomenon rather than the traditional focus in agenda-building studies on one single arena and what happens inside that arena. Societal agenda-building is a multi-arena process, without there being a clear authority deciding on the agenda. Kingdon (1984) provided the starting point for this analysis with his discussion of policy entrepreneurs and their skills, their networks, as well as how they can act on policy windows and other opportunities to forge a new, or change the existing, agenda. This converges with a point made in sociology: "Arenas and fora, and the various issues discussed and addressed there, [which] thus involve political activity but not necessarily legislative bodies and courts of law" (Strauss, 1978: 124). Such (always partial) entanglements can become locked-in into a forceful agenda, and then lead to path dependencies (Rip et al., 2007).

Figure 14.1, reproduced from Rip and Van Amerom (2009), maps the emerging paths in the evolution of the debate and activities and strategies. Time is on the horizontal axis, and the visualisation of the developments begins with promises about application of nanoparticles as voiced around 2000 and taken up by researchers and firms. The vertical axis comprises ongoing practices of production and use of nanoparticles, then meso-level activities of collective organisations (and of research and regulation), and macro-level societal debate. While there was already a general idea about the promises of nanotechnology, linked to the establishment of the USA National Nanotechnology Initiative in 2000, and some concerns were voiced based on speculative scenarios about run-away nano-robots, macro-level debate proper only started with a Canadian-based NGO (ETC group) issuing an early warning about risks of nanoparticles and calling for a moratorium on their development. This was resisted by nano-enactors, but was listened to during 2003 by governance actors such as the European Parliament and the UK government (see for details Rip and Van Amerom, 2009).

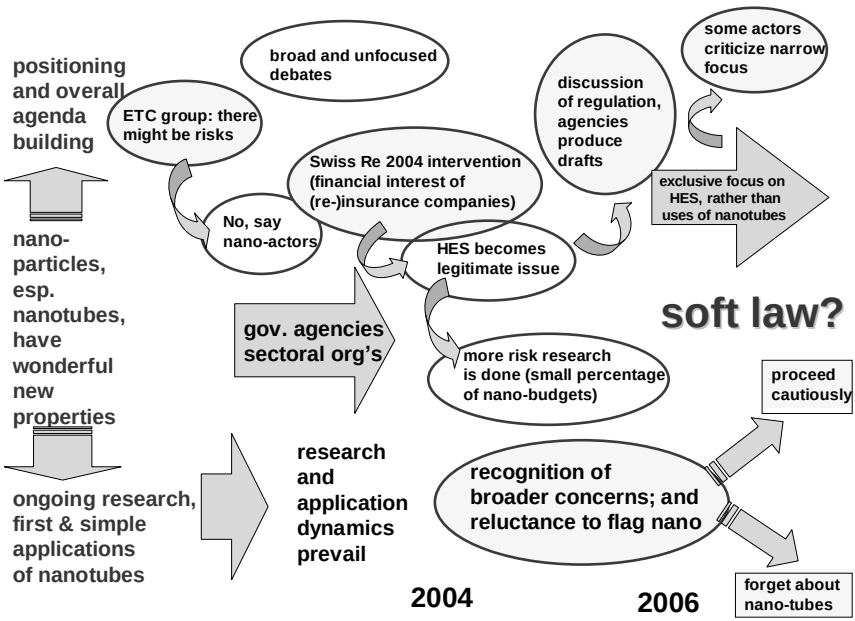

Figure 14.1. Evolving paths in the 'landscape' of nanoparticles and their risk

For my analysis of *de facto* governance, I highlight two points visible in the further developments. The first is that arenas overlap, and that actors, in practice, are not limited to their formal roles. Government actors with regulatory responsibility (especially those who are pro-active) attend meetings and generally take part in a variety of arenas where informal societal agendas are built. Industrial actors mingle with other kinds of actors, especially if a somewhat neutral space is provided. After the intervention in the debate, in 2004, by one of the main re-insurance companies Swiss Re, with a report arguing that carbon nanotubes might create risks similar to those of asbestos, risks of nanoparticles became a legitimate topic. A subsequent meeting organized by Swiss Re and the International Risk Governance Council (IRGC) in Zürich in July 2006 was an occasion for informal interactions.[7] The meeting discussed a (potentially authoritative) report on risk governance of nanotechnology authored by Renn (a risk and public deliberation scholar) and Roco (of the USA National

[7] The IRGC is a private not-for-profit foundation based in Geneva, "to support governments, industry, NGOs and other organisations in their efforts to understand and deal with major and global risks facing society and to foster public confidence in risk governance" (cited in Renn and Roco, 2006: 5). A conference report is available from Swiss Re Centre for Global Dialogue.

Nanotechnology Initiative). Governmental and industry actors from across the world attended, as well as NGOs and scientists and scholars studying nanotechnology in society. Dedicated workshops and mingling in the corridors allowed interaction and the recognition of positions of other actors (and thus some learning). What was very visible was the recurrent anticipation of (a) public reaction(s) (in co-evolutionary terms, this can be described as possibly leading to selection before-the-fact). Clearly, the traditional distinction between formal agenda-building by authoritative (policy) actors and informal societal *de facto* agenda-building becomes blurred. While one can nonetheless recognize, with Shibuya (1997), that for a risk issue to rise on the formal agenda it needs to be taken up in both formal and informal agenda-building processes, articulation and prioritization processes are clearly not separate.

The second point is how actual soft law, as with the recent voluntary reporting schemes of UK Defra and US EPA (cf. Kearnes and Rip, 2009), is not just a matter of a new government initiative. It is prepared through actors moving in new directions. As is visualized in Figure 14, such actors can be firms that realise they need to proceed cautiously and possibly assure credibility by being more transparent. Or regulatory actors recognising that there are openings for regulatory action but do not know exactly how to proceed. It is the combination of the two that creates a situation where soft law can be envisaged. And even then, there may not be much receptivity. Firms are reluctant to start reporting if they do not know what will be done with such data.[8] As Djelic and Andersson (2006: 378) note for transnational governance, "soft rules are generally associated with complex procedures of self-presentation, self-reporting and self-monitoring," and may thus lead to more organisation rather than less.

Interestingly, some companies do take the initiative. Codes of conduct are formulated (see further section 4), and a Risk Framework for Nanotechnology has been put forward by the unusual alliance of a big chemical firm (DuPont) and a non-profit group (Environmental Defense). The alliance was announced in June 2005.[9] Their eventual

[8] By July 2008, only nine companies had registered with the Defra scheme and EPA had received four submissions under the basic program (and commitments from 12 more companies), whilst no company has agreed to participate in the in-depth program. Interestingly, some branch organisations, recognizing the importance of the scheme for the credibility of the nanotechnology sector, tried to push their members to participate (see Kearnes and Rip, 2009).

[9] The two partners had a sense of the historical importance of their attempt when they announced it in an article in *Wall Street Journal*, 14 June 2005, under the title 'Let's Get NanoTech Right'. This echoes an earlier claim about how to handle nanotechnology: "Let's get it right the first time!" (Cf. Roco and Bainbridge, 2001).

risk framework, published in June 2007 following wide consultation is a substantial contribution, even if the alliance has come in for criticism from (other) NGOs and trade unions.[10] In the Executive Summary (7), the authors actually note the link with government regulation:

> "We believe that the adoption of this Framework can promote responsible development of nanotechnology products, facilitate public acceptance, and support the development of a practical model for reasonable governmental policy on nanotechnology safety."

In other words, actors now contribute to evolving governance arrangements in a reflexive manner.

The implications of this discussion of risk governance agenda building are two-fold. Firstly, that risk assessment in the real world and risk management and regulation are part of larger dynamics, are shaped by it, and their effects (their "success") are partly determined by these broader dynamics. One reason for the dominance of broader dynamics is the uncertainty about toxicity and exposure of nanotechnology materials (cf. Bowman and Hodge, 2006; Dorbeck-Jung, 2007). The point is general, however. The fate of risk assessments (i.e., their uptake and their "translation") is not determined by their own "internal" quality, but by their evolving contexts, which are influenced by other/earlier risk assessments and debates, in this case on genetically modified organisms, and earlier, on nuclear energy. Interestingly, in both earlier cases a storyline of the escape of modified micro-organisms and a run-away nuclear reactor occurred, horror stories which returned in the shape of nano-robots getting out of hand. Similarly, regulation is only one element in a range of governance activities and arrangements, which all operate at the interface between nanotechnology and policy/society and add up to a governance "landscape" (Kearnes and Rip, 2009). A key element of this landscape, and in a sense a precondition for regulation, is the process by which a *de facto* risk agenda emerged and shaped responses and interactions.

Secondly, the actions and reactions that build up to a socio-technical agenda, which solidifies and then shapes further actions and choices, create patchwork governance arrangements rather than a coherent system. This is clear in the way voluntary reporting and other soft law approaches are progressing (haltingly), as well as in the potential uptake of the DuPont & Environmental Defense Risk

[10] Partly in response, an "international coalition of [seven] consumer, public health, environmental, labor and civil society organisations spanning six continents called for strong, comprehensive oversight" of nanotechnology and nanomaterials. Their text has a strong precautionary thrust; "voluntary initiatives are not sufficient". Quoted from the press release, 1 August 2007 (www.nanowerk.com/news/newsid=2306.php). (accessed 26 February 2010).

Framework and the critical reactions to it. Such patchwork arrangements may well allow nanotechnological innovations to continue, and in that sense be seen as productive. They may turn out to be inadequate, however, when something untoward happens, for example when an unusual toxic effect surfaces. The only politically viable response then is to clamp down on nanotechnology in general and introduce harsh precautionary measures.[11] This is not an argument against patchwork governance arrangements, but an indication of inevitable trade-offs.

14.4. Discourse and Practice of Responsible Development of Nanotechnology

Whereas the reference to risk, and thus to possible regulation, created some coherence in the evolving patchwork, there is also more open-ended *de facto* governance occurring around nanotechnology, linked to phrases like "responsible development" and "responsible innovation", and in the USA, "responsible stewardship".[12] The implications are rarely spelled out systematically, but the thrust can be captured in this quote from the US National Research Council:

> Responsible development of nanotechnology can be characterized as the balancing of efforts to maximize the technology's positive contributions and minimize its negative consequences. Thus, responsible development involves an examination both of applications and of potential implications. It implies a commitment to develop and use technology to help meet the most pressing human and societal needs, while making every reasonable effort to anticipate and mitigate adverse implications or unintended consequences. (National Research Council, 2006: 73)

Clearly further development of nanotechnology is the main goal, but openings are created for considering "adverse implications or unintended consequences" and perhaps for doing something about them. This may invite nano-promoters to consider broader issues at an

[11] This is actually one of the three scenarios developed by Douglas Robinson for a Constructive Technology Assessment workshop on responsible innovation in nanotechnology, December 2007. See, for the methodology, Robinson (2009).

[12] See for example the proposal, in California, for a Nanotechnology and Advancement of New Opportunities (NANO) Act by Rep. Honda (D- San José): "The NANO Act requires the development of a nanotechnology research strategy that establishes research priorities for the federal government and industry that will ensure the development and responsible stewardship of nanotechnology."
Compare http://www.house.gov/apps/list/press/ca15_honda/NanoAct2008.html (accessed 26 February 2010).

early stage, and allow other actors to raise questions about the present direction of development.

European Commission documents on nanotechnology often refer to responsible innovation and, recently, a further step was taken by preparing and publishing a code of conduct for nanoscience and nanotechnology (N&N) research.[13] The restriction of the code to "research" was necessary, because of the limited remit of the European Commission in this respect, but the code is broader, and refers also to public understanding and the importance of precaution. There are explicit links to governance: the guidelines "are meant to give guidance on how to achieve good governance". As the Commission further specifies:

> [good governance of N&N research should take into account the need and desire of all stakeholders to be aware of the specific challenges and opportunities raised by N&N. A general culture of responsibility should be created in view of challenges and opportunities that may be raised in the future and that we cannot at present foresee.

A "general culture of responsibility" cannot be created by the European Commission, of course, but they clearly see themselves as contributing to such *de facto* governance.

USA and European government actors are not alone in pushing "responsible development". There are now also codes of conduct (specifically for nanotechnology) formulated by firms like BASF addressing the corporation's responsibilities to "our employees, customers, suppliers and society but also towards future generations",[14] and similar statements, for example by Degussa (now Evonik).[15] Recently, the Swiss retail industry went through the exercise of formulating a code.[16] Then there is also the recent initiative toward a "Responsible Nanotechnologies Code" led by a group consisting of the UK Royal Society, an NGO (Insight Investment), the Nanotechnology Industries Association, and supported by a network organised by the UK Department of Trade and Industry.[17] The proposed code goes much

[13] COM(2008)424 final, 7 February 2008: Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research.

[14] *Code of Conduct Nanotechnology,* http://www.basf.com/group/corporate/en/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct (accessed 26 February 2010).

[15] Degussa's website on nanotechnology has an item to this extent on responsibility (www.degussa-nano.com/nano). (accessed 26 February 2010).

[16] http://www.igdhs.ch/m/mandanten/175/download/CoC_Nanotechnologien_final_16_01_09_e.pdf (accessed 1 March 2010).

[17] See the May 2008 update at http://www.nanotechia.org/content/activities2/responsible-nano-code/ (accessed 26 February 2010).

further than merely the safe handling of nanotechnology, but it is not clear if and how it will be taken up. Negotiations about a final text that can be made public are still on-going.

There has been criticism of codes of conduct as being bland (though not all of them are) and as not specifying sanctions. Even so, they create openings for accountability. This does imply that it depends on others willing to call nano-enactors to account for whether the codes will have a real effect. While the discourse of responsible development will have implications for practices, broader issues referred to in the discourse will often be pushed to the background. The actual operationalisation of "responsible innovation" tends to focus on risk issues, transparency and some public dialogue; and in the case of industry, also as a responsibility for the safe handling of nano-production and nano-products.

While the recent emergence of Codes of Conduct (actual and proposed) already indicates distributed governance, they should be seen as the tip of an iceberg of anticipatory and reflexive actions and interactions that fill the gap between further the development of nanotechnologies and the actual and possible responses by society. There is a plethora of activities and gatherings in the nano-world with governance elements and/or implications, with explicit or implicit reference to responsible development. One can see them as emerging practices of discussion, deliberation, negotiation and participation.

In some cases, responsible development is a secondary effect. Definitions and standards for nanotechnology are of immediate importance for co-ordination among firms, but they will also be used to indicate the scope of regulation and of soft law like voluntary reporting. The International Organisation for Standardisation (ISO) has established working parties, and its standards are sometimes called "soft governance".[18] They are voluntary, but recognised as important and authoritative because of the process leading to them (expert working parties and wide consultation). Actors/stakeholders refer all the time to ISO standards and the working parties because they expect them to resolve uncertainty. The OECD has also become involved, and also looks at risks and public engagement; its working parties have a certain status and are expected to come up with authoritative conclusions. UNESCO has invested in a report on ethics of nanotechnology (UNESCO 2006). Further, dedicated groups or associations have been established, for example the International Council On Nanotechnology (ICON) has collected many stakeholders (but almost no NGOs). A web of activities and interactions results, and

[18] See presentation by Peter Hatto (ISO) at the International Dialogue meeting, Brussels, March 2008. (Tomellini and Giordani, 2008).

actors in the nano-world can refer to it to show that responsible development is being taken seriously.

Policy actors and nanotechnology spokespersons from industry try to keep abreast of what is happening and thus monitor the evolution of the discourse and the positioning of the various actors and groups. The director of the nanotechnology R&D programme in the European Commission's 6th and 7th Framework Programmes (until September 2008), Renzo Tomellini, often showed a slide with an overview (Figure 14.2). The fact that he shows it, and updates it, is just as important as the content of the slide.[19] The link with responsible development is clear in his mind. When (in meetings in 2007) presenting data on public opinion about nanotechnology, he was happy to note that the European public is more positive than the North-American public. "So we have done a good job. But this trust in us also creates a responsibility to make sure that nanotechnology is developed in the right way."

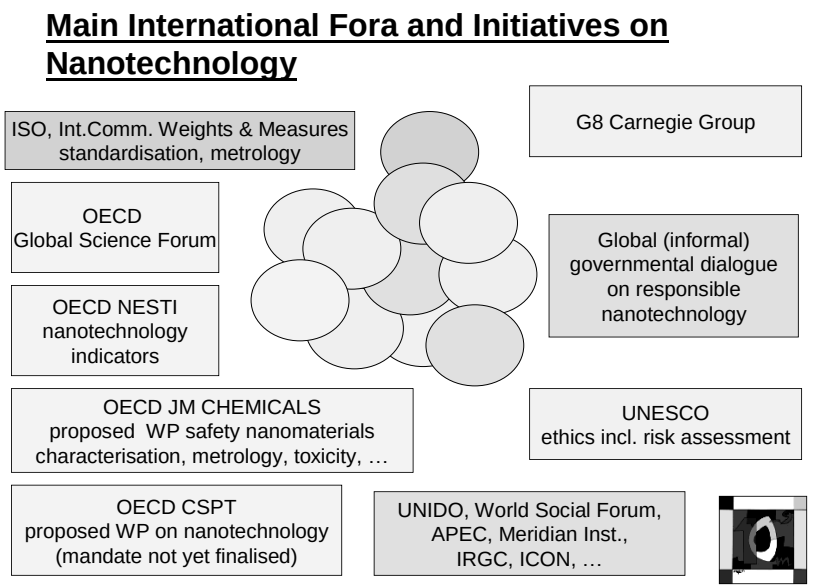

Figure 14.2. Tomellini's overview of activities in the nano-world (version Summer 2007)

[19] There is now an official version (without the clouds in the middle), published on Cordis. ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/a-interactions-global.pdf (accessed 26 February 2010).

Another action that is particularly interesting for what it might do (rather than what it does at the moment) is the International Dialogue on Responsible Development of Nanoscience and Nanotechnology, set in motion by Mike Roco (US National Nanotechnology Initiative) and Renzo Tomellini (European Commission's Nanotechnology Program) in 2004, and perhaps now gathering a momentum of its own. The idea was and is to have informal interactions between government officials and other actors in the nano-world, with reference to responsible development as one reason why coordination is important. After the first meeting in Alexandria, Virginia (Meridian Institute 2004), there was a delay because of political difficulties, but then meetings were held in Tokyo (2006) and Brussels (2008), with a next meeting planned in Russia. Such meetings offer reporting on developments, including ethical, legal and social aspects (ELSA) and experiences with public dialogues, but are also space for interaction. Their advantage is that they can be inclusive: there is no official mandate or link to an authority, so no actual or symbolic barriers to participation.

The key point to draw out of this mapping of activities is how a variety of actors begin discussing responsible development of nano-technology, refer to it, and develop relevant activities, and how the discourse shows some convergence. This may be the beginning of a shift in governance, driven by prudence and some good intentions, as well as the need to maintain legitimacy. Policy actors may be involved, but often interactively rather than stipulating a governance arrangement, and they build on receptivity to the discourse on responsible development that is clearly out there. Thus, there is some *de facto* governance of nanotechnologies. A subsequent question then is whether this is specific to the nature and situation of nanotechnologies, or whether it reflects a general shift in governance, in the direction of reflexive modernization (Beck, 1992; Beck et al., 2003)? The latter will be the case, definitely, but nanotechnologies offer a "lead" domain where the shift is visible, and is, in a sense, experimented with.

14.5. An Overarching Pattern?

There are more activities and emerging structures to be mapped, not necessarily specific to nanotechnologies, but taken up in earnest there. Upstream public engagement, including citizen conferences after the Danish model, is one example (Kearnes et al., 2006), the interest in having ELSA (Ethical, Legal and Social Aspects) included in the big

nano-research funding programs in the USA and Europe another.[20] Together with codes of conduct of varying status, and emerging soft law with a precautionary flavour, these fill the gap between promotion and control of nanotechnologies. Thus, the traditional governance arrangement of new technologies is shifting. The new activities and interactions are expected, and this will orient (enable and constrain) strategies, actions and interactions, and will be seen as legitimate.

We see an emerging overarching pattern, but its strength and eventual shape are still unclear. A key component of the pattern is anticipatory governance, and in particular, the consideration, at an early stage, of eventual societal embedding, including an acceptance of some responsibility. Will what is still mainly discourse become a practice, and a practice of *de facto* governance at that? To explore this question further, I will mobilize insights from STS and economics of innovation, because there is a structural similarity with patterns that have emerged in technological development *per se*.

Evolutionary economics and sociology of technological development have identified (and theorized) so-called "trajectories" of development at two levels. There are paths of successive specific designs and products, related to what Dosi (1982) called the "technological paradigm", which shapes expectations about productive directions of development and thus defines requirements. Nelson and Winter (1977: 56) refer to technicians' beliefs about what is feasible or at least worth attempting.

> When such beliefs and corresponding design and development practices are entrenched, one can speak of a "technological regime" determining technological decisions. An example is how the advent of the DC3 aircraft in the 1930's defined a particular technological regime: metal skin, low wing, piston powered planes. Engineers had some strong notions regarding the potential of this regime. For more than two decades innovation in aircraft design essentially involved better exploitation of this potential; improving the engines, enlarging the planes, making them more efficient.

Then, there are broad design heuristics or guidelines like mechanisation (since the 19th century), and automation (from the 1950s onwards), what Nelson & Winter (1977) called a "natural trajectory" and I will call a second-order trajectory to bring out the relation to technology-specific and thus first-order trajectories.

In specific developments in biotechnology, genomics, stem cells, and nanotechnologies, one can find first-order trajectories, some still

[20] The USA National Nanotechnology Initiative has funded two big Centers for Nanotechnology in Society, and some smaller units. See NanoNed (www.nanoned.nl). (accessed 26 February 2010).

emerging, others already established. For micro- and nanotechnologies, there is a second-order trajectory of miniaturization. Such overall requirements on the development of new technologies constitute a governance pattern. My additional point now is that the requirements need not be limited to those that specify technical performance.[21]

At present, for all newly emerging technologies, one sees attempts to include societal aspects and to anticipate on embedding in society. Already due to credibility pressures, such anticipation functions as a soft limit on specific developments. Thus, one can hypothesize that a further second-order trajectory may emerge, which could be labelled "working towards the adequate societal embedding" of technology. There is no guarantee that it will indeed become a trajectory of technological development even if policy actors are keen on it, as is visible in the discourse of "responsible innovation". Just as with mechanization and automation, the second-order trajectory of "working towards adequate societal embedding" need not be taken up in all concrete developments for it to function as a governance arrangement. But there must be sufficient actual uptake, and broad reference to anticipation on societal embedding to make it a second-order trajectory. This emerging second-order trajectory is not specific for nanotechnology, but it is in this area that the indicators are strongest – it is the lead technological domain for the trajectory.

Part of such a second-order trajectory seems to be in place already: the inclusion of EHS (Environmental, Health, and Safety) aspects in technological developments at an early stage. This actually builds on what one could call an earlier internalization of requirements from the selection environment: the chemical industry's Responsible Care programme in the 1990s (King and Lenox, 2000). It is significant that firms presenting a code of conduct (or similar) for nanotechnology are chemical companies. The focus on EHS may create a lock-in: in nanotechnology, as well as for other new technologies like GMO, adequate societal embedding will quickly be reduced to EHS aspects. Some actors, however, like Degussa (a chemical company) do emphasize the importance of responsibility and dialogue, and attempt to interact with new actors like critical NGOs. It is uncertain whether such operationalisations of broader anticipation will be successfully internalised.

An indirect indicator of internalisation is that funding agencies start creating special programs on ELSA and societally responsible

[21] While used in another context, the notion of meta-rules of the game (Djelic and Andersson, 2006: 385, 391) indicates a similar phenomenon.

innovation.[22] In a sense, funding agencies are "third parties": they do not develop (nano)technology themselves, but influence developments through their actions.[23] Capital providers like banks and pension funds (and perhaps even venture capitalists looking further than an immediate return on investment) might play such a third-party role as well, where they were to introduce requirements of responsible development. When funding agencies and other sponsors of research and development actually require anticipation on adequate societal embedding, nano-enactors have to develop relevant competencies, and this will contribute to a solidification of the arrangement.

14.6. In Conclusion

Broadening the notion of governance has enabled me to discuss *de facto* governance, both in general and how it occurs in the domain of nanotechnology. There were attempts at intentional governance, addressing uncertainties around an emerging technology, but their fate had to be understood against the backdrop of evolving *de facto* governance. The importance of societal agenda building through the interactions of actors and their strategies was clear. For risk governance, our understanding of such emerging patterns might be used to create scenarios of possible futures, to improve anticipatory governance, or at least to increase reflexivity. The discourse of responsible development also showed a mixture of efforts towards intentional governing (as in the case of the European Commission's Code of Conduct for N&N research), actors' initiatives and emerging patterns in a web of interactions creating orderings in the world of nanotechnologies. These are general features of *de facto* governance.

What was striking in the emerging *de facto* governance of nanotechnologies was the role of anticipation. Actors anticipate both possible futures as well as the reactions of other actors. This is more

[22] In the Netherlands, such a program has just started; it focuses on (a) advanced (emerging) technologies and (b) sociotechnical system transitions (www.nwo.nl/mvi). (accessed 26 February 2010). In Norway, the theme is ELSA of biotech, nanotech and neurotech (www.forskningsradet.no). (accessed 26 February 2010). In both cases, interaction between social science and humanities on the one hand and science and engineering on the other is an important requirement. In the UK, the Engineering and Physical Sciences Research Council (EPSRC) established a Societal Issues Panel in 2006 and experimented with dialogue. In the words of a participant observer: "an emergent sociotechnical imaginary that takes 'societal issues' not as an obstacle but as an active contributor to framing the work of the research councils" (Doubleday, 2008).

[23] Analytically, the importance of such "third parties" taking initiatives is that they can break through waiting games and other impasses that occur often in two-party games (Scharpf, 1997). An example of such a breakthrough is the intervention of re-insurance company Swiss Re in the risk debate (see section 3).

than prudence: newly emerging technologies like nanotechnologies create openings (opportunities as well as some concerns) that are uncertain by definition. The future becomes a reference point, even if it is unknown. One can speak of the "shadow of the future", in the same vein as Scharpf (1997) talks of the "shadow of hierarchy". Scharpf uses the metaphor of "shadows" more widely than simply in reference to hierarchy, e.g. "in the shadow" of the majority vote (191) or "in the shadow" of a statute (202), without being explicit about the actual mechanisms and dynamics at play (other than his reference to anticipated reactions when discussing decision making in bureaucracies (200)). For Scharpf, a key notion is "authority structure" and how this can be referred to and thus have effects in an indirect way. Thus, for new and emerging technologies like nanotechnologies, "the future", when articulated in more or less forceful societal agendas and expectations about responsible development, functions as an authority structure and thus casts its shadow on choices and actions in the here and now.

De facto governance is distributed, almost by definition, and cannot be easily shaped from a central point. This introduces ambivalence in the role of governance actors like governments. They have to give up on the assurance of governability as lots of things are outside their power and influence. At the same time, there is *de facto* governability: social orders are there and are (somewhat) effective, even if the direction may not be ideal. Moreover, one can see intentional and *de facto* governance co-evolving, and governance actors might then see their role as one of modulating this co-evolution (Rip, 2006).[24] Where UK Defra and US EPA opted for voluntary reporting, they hoped to draw on a sense of responsibility of firms, but clearly they were too early to effectively modulate: the evolution on the other side had not progressed sufficiently (the situation might be different in continental Europe). The International Dialogue discussed in section 4 began instead from the other side: while government actors were involved, they do not govern, but create instead a space in which *de facto* governance might be stimulated. Modulation of co-evolution also occurs in the public dialogues, in the creation of voluntary codes and responses by civil-society actors, and in technology assessment interactions visible in the world of nanotechnologies. It is explicitly mentioned in the recent calls for "midstream modulation" (Fisher et

[24] This is similar to what Andrew Dunsire (1996) has called "collibration" – an intervention to shift the pre-existing balance between countervailing forces. Institutional arrangements that have the effect of strengthening one or weakening the other of these forces will require much less energy than institutions that would have to stop an unopposed force. (Taken from Scharpf, 1997: 182).

al., 2006) and in midstream public engagement (Joly and Rip, 2007). The work of governing is distributed, and may become partially internalized when regimes stabilize. The possibility of a second-order trajectory where working towards adequate societal embedding as a requirement of ongoing technological developments is a particular, and particularly interesting, case.

Even without a fully fledged second-order trajectory, nano-enactors already take initiatives by themselves or stimulated by third parties. This works out differently in the various domains under the umbrella term "nanotechnology". For new materials, chemical companies have relevant competencies because of the earlier (and continuing) Responsible Care Programme, and they feel credibility pressures. It is in this sector that firms have come up with nanotechnology codes of conduct. Micro-electronics firms, on the other hand, which do a lot of work at the nano-scale, are far removed from end users (even if they try to create some visibility, as with labels "Intel inside" on laptops). There are discussions, for example about RFID and about ambient intelligent systems enabled by nanotechnology, but there other firms take the lead.[25] Big incumbents have the resources to be pro-active, but do not always rise to the occasion. In bio-nanotechnology, the third main domain of nanotechnology, the big pharmaceutical companies are interested, but tend to wait for small firms to come up with nano-enabled innovations like diagnostic devices and drug delivery. For small firms, their first concern is survival, and broader anticipation is a luxury. Third parties like insurance companies may be able to (sometimes inadvertently) modulate productively. Other input in the *de facto* governance of nanotechnologies is likely to come from interactions across the product-value chains. The first signs of this are linked to health and environmental issues.

Thus, *de facto* governance is not blind. It is shot through with attempts at shaping, and by their residues, somewhat stabilized regimes around nanotechnologies, and newly emerging technologies more generally. The question of the quality of such governance, e.g. governability, legitimacy and the directions that are pushed, is important but remains difficult to consider since no one actor is specifically responsible. However, as soon as regimes and second-order trajectories appear, these offer entrance points for critical evaluation and perhaps attempts at changing them – by modulation.

[25] Firms like Philips and Siemens, who used to cover both sectors, have now divested their micro-electronics development and production.

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Chapter 15. Ten dimensions of technology regulation. Finding your bearings in the research space of an emerging discipline

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Abstract
We are at the start of what may be emerging as a new discipline of academic study: technology regulation, the study of how technologies are or should be regulated. With a broad definition of technology – the wide range of tools and crafts that people use to change or adapt to their environment – and of regulation – the intentional influencing of someone's or something's behaviour – this is a wide-ranging and complex field indeed. To get a grip on this emerging field, we need theoretical grounding. So far, few attempts have been made to map the space in which regulators and researchers who deal with technology regulation move. This chapter provides a first, essayistic attempt at comprehensively mapping the space of the emerging field of technology regulation by distinguishing and describing the ten dimensions that together span up this space. Starting with technology-related dimensions (type of technology, degree of innovation, place, and time), it moves on via regulation-related dimensions (type of regulation, normative outlook, and knowledge) to research-related dimensions (discipline, problem definition, and frame). The articulation of technology regulation as a ten-dimensional space is an analytic tool that may help us to understand what this emerging discipline is about, how it approaches its research, which known unknowns need to be researched, and to get an intuition of the unknown unknowns that await us out there when we further travel in technology regulation research space.

15.1. Introduction

When I studied mathematics, I was always fascinated by multi-dimensional spaces. For a mathematical problem, it doesn't fundamentally matter whether you're dealing with two, four, or sixty-three dimensions (granted, calculating problems in 63-dimensional space is perhaps somewhat more complex than solving a two-dimensional equation). Unlike some mathematicians and all computers, most people – myself included – have difficulty in visualising and dealing with a problem in a space with more than three or four dimensions.

The difficulty of handling more than three or four dimensions stems of course from the fact that our universe is spanned up by three spatial dimensions and one temporal dimension. Or rather, we humans

perceive the universe as being spanned up by these four dimensions. If we are to believe fundamental scientists in quest of the Theory of Everything, timespace is actually spanned up by ten or eleven dimensions. We only perceive four of them – the others are compacted away beyond human perception (unless your brain happens to have the perceptive and imaginative qualities of the likes of Albert Einstein or Stephen Hawking).

Perhaps a similar mechanism occurs in technology regulation. When we define, attack, and solve problems in technology regulation, we have difficulty in dealing with more than three or four dimensions. The problem as we perceive it may well be addressed in this manner – we are only human, after all – but the underlying mechanisms are often infinitely more complex and multi-faceted, leading to a limited understanding of the real problem (whatever that may be) or of the full thrust of a solution we come up with.

Technology regulation certainly is a multi-dimensional space. Academics and regulators have realised this for many years, and the papers in this volume again show ample evidence of the complexities of technology regulation. But do we actually understand *how* complex it is, and how many different perspectives are involved? To do so, we should at least bring together insights from various legal fields, legal theory, governance studies, ethics, policy studies, public administration, political science, media and communications theory, science & technology studies, and philosophy of technology, to name the most obviously relevant fields, along with different fields of science and technology itself. One of the aims of the conference that lay at the basis of this volume was to bring together scholars from these different disciplines, to discuss together topical problems in the field of technology regulation. As the contributions to this volume demonstrate, the topics and issues we are dealing with bear some close resemblances and interrelations, but they are also quite varying and divergent, as they move along different lines of research. Nevertheless, they are all moving around in the same space – the space of technology regulation research.

As I perceive it, we are at the start of what may be emerging as a new discipline of academic study: technology regulation. 'Technology regulation' here indicates the study of how technologies are or should be regulated, technologies being the broad range of tools and crafts that people use to change or adapt to their environment, and regulation being the intentional influencing of someone's or something's behaviour.

It is actually too early to speak of an emerging discipline yet, but the contours are certainly appearing on the map: all around the world, conferences, journals, and research centres are emerging devoted to

technology regulation. Not all of these cover the full range of issues that fall within the broad scope of my working definition of technology regulation, which ranges from bio-ethics to innovation theory and from intellectual property to cybercrime, but increasing ties between the diverse researchers and research centres facilitate an exchange of ideas and insights across the board.

Let us assume that at some point, technology regulation will indeed emerge as a new discipline, or at the very least as a broadly studied field of trans-disciplinary research. To get a grip on this multi-dimensional field of technology regulation, we need theoretical grounding. Unsurprisingly for an emerging field, technology regulation is rather under-theorised so far, and few attempts having been made to map the space. To be sure, attempts at theorising have been made that, even if they do no fulfil the promise of their comprehensive titles, provide relevant insights into technology regulation (Cockfield and Pridmore, 2007; Mandel, 2007), but these do not aim to comprehensively describe all relevant factors that are at issue in technology regulation. For space mapping, perhaps Roger Brownsword (2008) comes closest in the introductory chapter to his *Rights, Regulation, and the Technological Revolution*, in which he succinctly lists key regulatory aspects for the technologies of the 21st century, including regulatory styles, modes, pitch, phasing, and range. Roger Brownsword and Han Somsen (2009) have also sketched major contours of technology regulation in their introductory article to the new journal *Law, Innovation and Technology*.

Perhaps technology regulation need not go as far as developing a superstring theory or M-theory of fundamental physics, let alone a Theory of Everything, at this stage of its development. But it certainly is useful to attempt to further map the space in which the researchers of technology regulation travel, for two reasons. Firstly, determining the axes of the multi-dimensional space that constitutes technology regulation research will help us to get a grip on where we are, to find our bearings by seeing the co-ordinates of our point in space, and to become more aware of those other dimensions that influence our state of being beyond the three or four visible ones. Secondly, once we see more clearly where we are and what space surrounds us, we can look ahead to those areas of the universe that are as yet unexplored. Knowing the dimensions of technology regulation research can help us to define future research agendas and to set our course accordingly, taking on board new disciplines and insights along the way as we come to understand better what we need for solving the known and unknown problems that await us 'out there'.

In this chapter, I provide an attempt at comprehensively mapping the dimensions of the emerging field of technology regulation research.

Within the limitations of this book, this can only be done in a sketchy and provisional way, and this chapter should be read as an essay proposing one way in which the universe of technology regulation can be perceived. If this essayistic map helps researchers or regulators to some extent to find their bearings or to see interesting paths for future research, my aim will be more than fulfilled.

15.2. Ten Dimensions

To see where you are, or where you want to go, in technology regulation (TR) research space, all you have to do is determine the coordinates along ten different dimensions. Starting with technology-related dimensions, we move on via regulation-related dimensions to research-related dimensions. Just step on board and travel along.

15.2.1. Technology Type

The first and most obvious dimension to begin with is the type of technology at issue. Since 'technology' refers to the broad range of tools and crafts that people use to change or adapt to their environment, many different types of technologies can be the focus of research, and obviously, the questions raised by a certain development in technology depend very much on the character and level of abstraction of the technology at issue.

In terms of character of technology, we can look at seemingly simple material applications, for example bicycles, bakelite, and (light) bulbs, in the attractively alliterative analysis of Wiebe Bijker (1995), or at modern-day innovations in materials such as nano-products (Schellekens*; Gammel et al.*) and chemical substances (Versluis et al.*). Information and communication technologies (ICT) have different characteristics from material technologies, in that the concerns raised by ICT often reside not only in their physical aspect – hardware, electrons, quantum bits – but also, and often more pertinently, in their immaterial, virtual aspect – cyberspace (wherever that space may be), information, and knowledge (Hildebrandt*; Hendry and Goodall*). And while these technologies can be characterised as 'thing-related' technologies, yet other issues are raised by 'life-related' technologies, meaning technologies that impact or use organic or living bodies, such as plants through GMOs (Van Asselt et al.*) or humans through embryo-affecting technologies (Gavaghan*; Zeegers*), or other applications of human biotechnology, genetics, or neuro-technologies. And as we travel along the axis of technology, we

* An asterisk denotes that the paper referred to is included in this volume. It is therefore not listed separately in the References section.

will observe that, increasingly, these different types of technologies are being combined in what is usually termed 'converging technologies' or NBIC (nano-bio-info-cogno technologies), for example in nano-medicine (Dorbeck-Jung*), bio-computing, or synthetic biology. This alone is a sufficient reason to bring together scholars from different fields to jointly study technology regulation, since insights from different technology fields must be combined as technologies converge.

The level of abstraction is also a feature of the technology dimension. We can look at very concrete applications of a certain technology, such as Facebook (Hendry and Goodall*) or the creation of hybrid human-animal embryos (Zeegers*). At the other end of the spectrum, 'technology' can be studied as a phenomenon in itself, for example how people interrelate with pervasive 'technoscience' today and tomorrow (Zwart*). Most research is situated somewhere in between the very concrete application and the very concept of technology; this ranges from the somewhat concrete – web 2.0, nano-medicine, or psycho-pharmaceuticals – to a more abstract category like ICT or neuro-technologies.

15.2.2. Innovation

Some technologies seem plain and well-known; we are so used to them in everyday life that our brain hiccups for a fraction of a second when you refer to a ballpoint, a brick, or a pair of glasses as 'a technology'. At one point in time, however, these were radical innovations. Other technologies seem completely new today; brain-controlled bionic limbs or colour-changing nano-coatings sound like science fiction rather than *Science* facts to most people, even though they have featured on the research agenda for several years, and at some point in time they may become as plain as a plane. The degree of innovation clearly is a relevant dimension in technology regulation research. Well-known, 'more-of-the-same' technology applications will usually fall within the scope of existing legislation or other regulatory instruments, in contrast to radically new technologies.

This is a different dimension from the first, since the type of technology is, in principle, independent from how innovative it is. Although we talk easily of 'new technologies' or 'emerging technologies', often with the implicit or explicit understanding that we refer to nano-technologies, neuro-technologies or converging technologies, the applications in these fields need not always be 'new' or 'emerging', but may simply be an improved version of existing tools. And conversely, 'old technologies' can also deliver innovative applications; some of the most exciting developments today take place in, for example, synthetic materials, robotics, and cars. Admittedly,

most of these developments involve some form of ICT or biotechnology, underlining the increasing interwovenness of the branches of science and technology. But in principle, any type of technology can yield both more-of-the-same and very innovative tools and crafts.

The degree of innovation is relevant for regulatory research, not because innovative technologies raise more questions than non-innovative ones, but because the type of questions at issue differ. With 'large' innovations, research will tend to be exploratory in nature and focus on the core effects of the innovation at issue. 'Small' innovations can lead to more analytic questions of compliance or the exact formulation of rules, and often, regulatory implications of unforeseen side-effects will be the object of scrutiny – sometimes, a small step for a technology (such as embedding a text message option in mobile phones) turns out to constitute a giant leap for society (changing patterns of language and communication). It is also important to realise that the degree of innovation need not always lie in the quality of a technology, but that quantity is equally important. It is far from rare that a change in the scale of a technology gives rise to significant regulatory questions, for example with cryptography (becoming almost impossible to crack when based on mathematical algorithms instead of traditional ciphers) or with biobanks for medical research (yielding new types of information when interconnected on a massive scale). Here, innovation arising from quantitative steps can have truly qualitative implications.

15.2.3. Place

An obvious dimension, if only because it is the one most associated with our understanding of space, is place. Where a technology is developed or used, in which environment, in what kind of organisation – these are all relevant factors for appreciating the implications of a given technology. Even though globalisation and the increasingly international organisation of science and technology imply that technological innovations travel far and fast nowadays, this by no means implies that technologies evolve in a global 'technospace' without local, national, or regional geographical components. This applies *a fortiori* to regulation, which retains a strong geographical component however much international law, global governance, and international standardisation have gained ground over the past decades. Questions of technology regulation always have to take into account the location of both the technology and regulatory attempts, so that relevant socio-cultural, legal, economic, and institutional factors associated with that place can be factored in.

This applies as much to physical space as to virtual space, if we understand cyberspace or a virtual world to be a 'place' that exists in another realm than the computers, software, cables, and wireless waves that make this virtual space come into being. Virtual worlds also have socio-cultural, regulatory, economic, and institutional elements associated with their geography, which, depending on the perspective from which they are considered, will to a greater or lesser extent be connected with those of the physical locations where virtual space and real space intersect and interact.

15.2.4. Time

As it is the fourth dimension in timespace, so is time the fourth dimension in TR research space. Time is essential for technology and for regulation. This dimension to a large extent corresponds with the temporal development cycle of technology: from fundamental science to applied science, and from research & development via product development to product marketing and product use. The various stages of technology development involve different regulatory issues, although some elements – such as distribution of responsibility and the social shaping of technology – feature in each stage. Regulatory issues in the earliest stages of fundamental research may focus on long-term, large-impact effects and scenario forecasting of a technology *in abstracto*, while the latter stages of technology marketing and use can focus on short-term effects of concrete applications. But of course the reverse is also possible: one can ask concrete questions about health and safety regulations for fundamental research of nanotubes, and study the long-term effects on identity of social-network sites.

Many issues along the time dimension relate to the question of when regulators can or should intervene if they want or ought to regulate. Collingridge's dilemma is perhaps the most pertinent formulation of the challenges of time: controlling a technology is difficult in its early stages because not enough is known of its possible or probable effects, and it is also difficult once the technology is well-developed because by then intervention is expensive and drastic (see Van Asselt et al.*). A major challenge for research is therefore to find ways to regulate in early stages when it is still possible – albeit in the dark – to regulate, which calls for innovative approaches (Rip*; Mandel, 2009).

Challenging as the dilemma was in 1980 when Collingridge formulated it, it has become only more acute in light of 'technological turbulence', with short innovation cycles in, for example, the ICT sector. The Internet is a good example of another time-related phenomenon: namely, Gartner's hype cycle, which observes how technologies start with a trigger, rise to the peak of inflated expectations, only to plummet

in the trough of disillusionment, from which it can slowly climb the slope of enlightenment to finally reach the plateau of productivity (Fenn, 1995). Researchers of technology regulation may observe that regulation frequently follows a similar hype cycle in itself. Although the regulatory cycle can follow the technology cycle with a time lag, at other times it intervenes in the technology cycle by inflating expectations (regulating electronic signatures in the mid-1990s), pushing the technology into the abyss of disgrace (prohibiting embryonic stem-cell research in the US), or giving the technology a leg-up in its ascent of the slope of enlightenment (liberally handing out patents in biotechnology) (cf. Van den Daele*).

15.2.5. Regulation Type

With place and time, we have already come close to the more regulation-related dimensions of TR research space, where we have now arrived. The primary dimension in this region is the type of regulation at issue. As I use a broad notion of regulation – the intentional influencing of someone's or something's behaviour – this is a very rich dimension indeed. It comprises, for example, the regulatory 'toolbox', in which we find – depending on who crafted the toolbox – Lessig's (1999) four modalities of regulation (law, social norms, market, and architecture) or Hood's tools of government (nodality, authority, treasure, and organisation) (see the reappraisal of Hood by Raab and De Hert, 2008). Equally important are the actors wielding these instruments, the regulators (governments at different levels; NGOs; standardisation bodies; public-private partnerships, etc.), and the actors targeted by them, the regulatees, not to mention popular hybrids of these in the form of self-regulation and participatory governance. Moreover, these actors act within regulatory institutions, such as the EU regulatory framework, UN bureaucracy, or cybercultural Internet governance networks, which shapes the tools and actors as much as it is shaped by them. There is thus a significant interdependence between tools, actors, and institutions, which is why I have stretched them together along one axis of regulation type.

Further refinements can be made of different aspects of regulation type. Brownsword (2008: 16) has introduced regulatory 'pitch' as a relevant factor, i.e., in what tone of voice regulators speak to regulatees. They can use for example a paternalistic, command-and-control voice ('thou shalt not copy') or a soft-sisterly, caring voice ('do protect your e-banking password'), but also a practical voice ('introductory offer: biometric passports now with 20% discount!'). He also mentions regulatory range (Brownsword, 2008: 19-21): behaviour can be influenced by negative (stick) or positive (carrot) or neutral means. And these can again be implemented in different ways, for example a stick

to discourage undesirable behaviour can take the form of criminal, administrative, or civil sanctions. Many other aspects can be distinguished of regulation types that can help us to better understand this dimension. It is therefore highly relevant for technology regulation research to engage with scholars from legal theory, political science, policy studies, law & economics, and business administration.

15.2.6. Normative Outlook

Technology regulation does not take place in a neutral vacuum. On the contrary, since it focuses on influencing behaviour, normative elements enter the picture as a matter of course. The substantive goal of the regulation – which will of course always be normative in nature to a greater or lesser extent – is included in the previous dimension, since that is part and parcel of the regulation type. There is more to norms than the goal of regulation, however, and that is the normative outlook that underlies or implicitly feeds technology regulation. This can be a certain ethical paradigm, such as utilitarianism or communitarianism, a religious belief, or widely-shared values that are almost taken for granted in a certain community, such as individual autonomy in Western liberal democracies, kinship bonds in the South Pacific, or originality in the global academic research community.

Normative outlooks do not necessarily involve the most obvious normative paradigms such as ethics or religion. There are also more subtly normative assumptions that underlie regulatory decisions. For example, one's risk attitude or tolerance of risk is a hugely important factor in risk governance processes; risk-averse regulators will reach for precaution where risk-tolerant regulators may sooner adopt a wait-and-see or early-warning approach. This can be seen as an instance of what Brownsword (2008: 21) has termed 'regulatory tilt', i.e., the default position set by regulators, which can lean towards the permissive or the prohibitory side, and which is influenced by all kinds of underlying assumptions or attitudes. Uncertainty attitude could also be included here, which refers to the level of uncertainty that regulators can or want to cope with (Van Asselt et al.*).

Such normative outlooks are the substrata on which technology regulation is cultivated, and therefore significantly affect how concrete cases of technology regulation grow and flourish (or not). They are, however, rarely made explicit, and it is a primary task for TR research to expose how the implicit normative outlooks influence the process and outcome of technology regulation. For this reason, the normative outlook is an important dimension in its own right.

15.2.7. Knowledge

Uncertainty attitudes, and the associated 'uncertainty paradox' (Van Asselt et al.*), have much to do with the level of knowledge that is available. Here we encounter the dimension of knowledge, which should be seen as a separate dimension from normative outlooks; the latter focuses on knowledge on a meta-level (how we deal with knowledge), whereas the dimension of knowledge itself deals with its substance. It comprises what we know and how much (or how little) about a technology and its effects, about certain regulatory aspects, or about some instance of technology regulation. The major factors here are, in the well-known distinction from risk regulation, knowns and unknowns, with the useful distinction that there are known unknowns (we don't know how psycho-pharmaceuticals affect the brain in the long term) as well as unknown unknowns (we are not yet able to imagine all possible effects that nanomaterials may have on life, the universe, and everything). Particularly the unknown unknowns make technology regulation tricky, because we do not know exactly what types of ignorance or uncertainty we should focus our efforts on. Fortunately, unknown knowns may come to the rescue, i.e., things that we know but are unaware of as being relevant to the case at hand, for example, because they are common knowledge in a different field but unknown in the primary discipline from which a problem is approached. Unknown knowns are a category that is somewhat underappreciated in technology regulation. Bringing together different disciplines, which is one of the key aspects of TR research, may well bring to light unexpected insights that help to identify the relevant knowns and unknowns or to turn an unknown into a known. Technology regulatory challenges that we suspect of involving significant unknown unknowns can clearly benefit from structural transdisciplinary research or, as we may wish to call it, organised serendipity.

15.2.8. Discipline

Knowledge has brought us closer towards the end of our journey through TR research space, as we enter the region of research-related dimensions. The discipline or field of research itself is the primary dimension here. Along this axis the disciplines of academic research are spread out. Technology regulation can be researched from all kinds of disciplinary perspectives, including law and its subdisciplines, governance studies, ethics, policy studies, public administration, political science, economics, media studies, communications theory, psychology, sociology of technology, philosophy of technology, cybernetics, information theory, systems theory, robotics, genetics, neuroscience, and so on and so forth. Some of these fields are age-old;

others are very young, emerging on the map after years of multidisciplinary and interdisciplinary research to become a discipline in their own right. We need not go into the semantics of multi-, inter-, cross-, trans-, neo-, or post-disciplines here; for the purposes of this chapter, it suffices to note that the dimension of discipline is rich, diverse, and dynamic. What you research, and how you research it, is to a large extent defined by the research discipline you use. But it also works the other way around, since research disciplines evolve and are transformed by the gradual change in the research problems they deal with.

15.2.9. Problem

Technology regulation research is not random, but aims at addressing a certain issue, usually a problem in theory or practice. A crucial dimension of TR research space is therefore the problem definition. Is it the aim to understand how a certain mechanism works, in technology, in regulation, or in technology regulation? Is it to elucidate an emerging phenomenon, such as *de facto* regulation in early-stage nanotechnology development (Rip*)? Does the research focus on solving a problem in theory, such as how to overcome Parfit's dilemma (Gavaghan*) or how to reinvent the legal system after the advent of Ambient Intelligence (Hildebrandt*)? Or does it aim to solve a problem in regulation practice, for example, to consider what are the most satisfactory current regulatory regimes for regulating nanotechnologies (Bowman et al.*); or whether patent law is being applied adequately to stimulate innovation (Schellekens*)?

Problem definitions thus range from understanding something to solving something, and the consequent research involves approaches ranging from the purely descriptive through the analytical to the normative. Often, the type of problem and the type of approach go hand in hand, a descriptive approach usually being applied for enhancing understanding, a normative approach being applied for solving an actual problem. This is not necessarily the case, however: part of a solution to a regulatory problem may be to describe the known or possible consequences of various solutions, without taking a stance on which solution 'best' solves the problem; and a problem definition aimed at better understanding a certain mechanism, such as how regulatory interventions affect fundamental rights, can well be normative in character. This shows that researchers face a range of choices in the problem definition of what they want to address: what problem exactly do they target, what kind of problem is this, what is a suitable approach to addressing this problem, and what methods can or should be used for that?

Note that this dimension does not exclusively apply to researchers. Regulators also have to think about how they define the problem when they regulate. To address a regulatory problem, the same questions of problem definition and approach apply. Some such questions fall within the dimension of regulation type, but several questions are more preliminary than that, as regulators have to define the problem before they can go on to choosing regulatory instruments, involve actors, etc.

15.2.10. Frame

Whereas the 'problem' dimension deals with framing research questions, many other factors are also involved in 'framing' technology regulation research, in the sense of constraints that define the 'window' through which you view the world. It is useful to distinguish between these two kinds of framing: a) actively framing the problem in a certain way for research purposes and setting the parameters that you can play with (such as the type or scope of the problem), which is dimension no. 9, and b) finding oneself in a frame of reference that constrains the room for action. This constitutes a separate dimension, because many factors function as relevant research constraints. For example, the system bias of the organisation of research (which influences whether research is conducted in private or public institutions or public-private partnerships, in commercial or not-for-profit settings, with certain levels or types of researchers) affects the types of research that can be or are being done. Obviously, the available amount of money – and the ways in which it can be spent – also influences the research. Moreover, social norms (what is 'accepted' or 'acceptable' research) and ethical or legal research guidelines constrain the scope for research, for example to what extent experiments can be done with animals or humans. And all kinds of other biases – such as gender, cultural, or beliefs bias, for example when the world is perceived from the perspective of a WASP – affect the research. In short, similar to the way in which normative outlooks constrain the regulation region of TR space, the frame constrains the research region of TR space, often 'under the skin' and beyond the awareness of researchers or regulators. It is important to become aware of these constraints if the results of research are to be appreciated on their merit and limitations.

15.3. Finding Your Bearings in Research Space

So, what have we gained by having travelled through this ten-dimensional space? Hopefully, journeying, albeit briefly, along each consecutive dimension has elucidated the multi-faceted nature of technology regulation and has shown how complex it is to research technology regulation. Most dimensions will have been very obvious

but others were possibly less so. Becoming aware of all ten dimensions can help researchers as well as regulators to find their bearings in TR research space. To find out where we stand (or float, if we do not have ground to stand on), all we have to do is determine the ten co-ordinates in space of our current position. Although it remains impossible to graphically represent ten dimensions on two-dimensional paper, the following graph may help to represent the ten dimensions, grouped together by the three constitutive elements of technology regulation research.

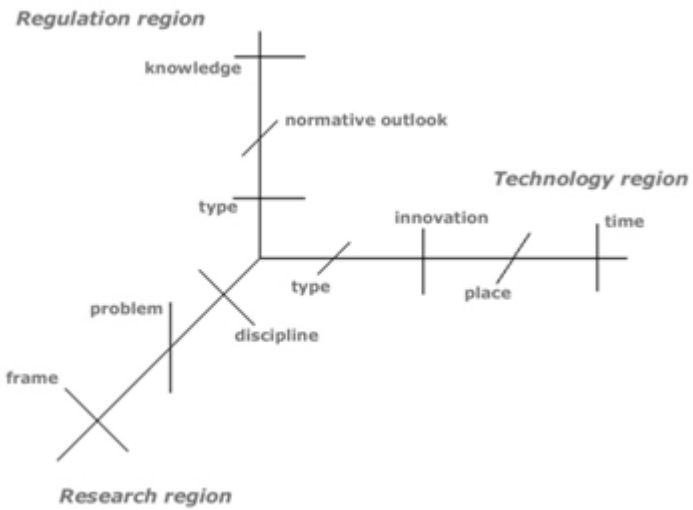

Figure 15.1. The ten dimensions of technology regulation research space

An assumption underlying this map of TR research space is that the dimensions are orthogonal, i.e., that they are independent from each other. This is a serious simplification, since in real life, no neat distinctions apply, and most things are related in some way or another. Certain dimensions are no doubt interrelated to some degree, such as the normative outlook that feeds regulation and the framing constraints of an associated research problem, or the type of technology and the discipline that studies its regulation. I am sure, too, that my own frame of reference has affected my drawing the map in this way, being influenced, for example, by a Western liberal-democratic background, working in a law faculty, and a mathematician's predilection for dimensions. Other researchers may distinguish certain other dimensions, or in fact group all the aspects of TR research in a

somewhat different way based on other metaphors than multi-dimensional space. The map drawn here does not pretend to be, literally, a map of 'real' space. It is a map that may help travellers in technology regulation research to determine their coordinates by providing a checklist to look around and take into account all possibly relevant aspects.

To illustrate how the map could be used, take a look at, for example, the chapter in this volume by Bärbel Dorbeck-Jung*. We can situate her contribution in the upper regions of the map: the dimensions most visible in her analysis are regulation type, knowledge, and innovation. The paper is a quest for prudent *types of regulation* for a technology – nanomedicine – that raises problems because its *innovativeness* (nano-structures calling into question the distinction between medicinal products, medical devices, and biologic products) causes gaps in *knowledge*, not only in terms of uncertain risks associated with nanomedicine but also in terms of the applicability of existing regulatory regimes. Interestingly, the dimensions of innovation and knowledge are not only active in the problem definition, but also in the search for solutions: knowledge gained in the regulation of adjacent technologies (medical products, in particular advanced therapy medicinal products) may show good practices that can help to regulate nanomedicine, applying an innovative approach to regulation of 'prudent regulatory hybridisation'.

Albeit less visible in the main argument of Dorbeck-Jung's chapter, other dimensions nevertheless also play a role. The problem at hand is triggered partly by nanomedicine being a hybrid *type of technology* – nanotechnology applied in the life sciences – in a *temporal* state of rapid development that calls for continual vigilance throughout the entire regulatory product cycle. The *place* of action is Europe, which brings along a *normative outlook* of democratic values of, *inter alia*, openness and participation that influence the direction of regulatory solutions. It would be interesting to conduct a comparable analysis for other places, such as South-East Asia or the United States, and see whether their regulatory traditions and attitudes to risk and uncertainty lead to similar preferences for hybrid forms of soft-law and hard-law regulation, and whether in their regulatory contexts, nanomedicine is also seen as problematic for the way in which it blurs the distinction between medicine, device, and biologic product that underlies health regulation. Moreover, the analysis is grounded in the *discipline* of governance studies, but also draws upon valuable insights from legal theory and Science & Technology Studies. It might be further enriched by scholars who could incorporate insights from other fields, such as systems theory, with knowledge of how hybridisation processes of different systems work. Finally, it could also be an interesting exercise

to analyse how the problem definition – "what lessons can the regulation of nanomedical products learn from the European Union's medical product regulation?" – is *framed* by the presentation of the latter as an example of 'prudent' regulation, with the epithet subtly leading the reader to have an uncritically favourable attitude to hybridisation of regulation: surely, no-one would advocate 'imprudent' regulation that sticks to monolithic forms of regulation? The underlying assumption is that hybridisation of regulation – merging soft-law and hard-law elements – will combine the best of both worlds rather than lead to a lose-lose situation; this may not be an unwise assumption, but it could do no harm to test it explicitly, perhaps in ex-ante evaluation of proposed regulatory solutions, or in continual vigilance of the regulatory cycle of emerging nanomedicine regulation.

The map of dimensions of technology regulation space can be used in this way as a heuristic tool to position research – *ex post*, as I have done here, but also *ex ante* by researchers embarking on writing a paper – and therewith show the major directions in its argument. Perhaps more importantly, it also elucidates its less-developed elements, which can point the way to relevant questions for further research. It would be a great exercise to do a similar mapping of the other chapters in this volume, in order to come up with a comprehensive agenda for future research, but I am running out of space here and will leave this exercise to the imagination of the reader in her role of armchair traveller.

15.4. To Boldly Go

As I indicated in the introduction, I have presented here an essayistic attempt to comprehensively map the dimensions of the technology regulation research. I am open to other maps, as well as to other metaphorical representations of the field we operate in. What is important, I think, is to support the emerging discipline to gain some foothold in terms of analytic tools that help us understand what this discipline is about, how it approaches its research, what it can contribute to the body of knowledge, which known unknowns need to be researched, and, most excitingly, to get an intuition of the unknown unknowns that await us out there when we travel further in TR research space.

As the contributions to this volume attest, technology regulation can be fruitfully studied from many different perspectives and disciplines. But ultimately, it is the combination and integration of the many perspectives and research backgrounds that moves the field forward onto another level of understanding of how technology interacts with society, how regulation responds to and intervenes in

this interaction, and how regulation at the same time is shaped by the interaction of technological and social developments.

Bringing together various researchers and their insights into a single volume is more than an act of book-binding – it is an act of research-binding and discipline-building as well. Technology regulation makes up a most complex multi-dimensional space, but with joined forces, we are well equipped to embark on the journey to explore unknown parts of the universe. To ask questions that no-one has asked before. To boldly go, where no researcher has gone before.

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